# Harnessing Intellectual Property Rights for Development Objectives

***The Double Role of IPRs***
***in the***
***Context of Facilitating MDGs Nos. 1 and 6***

**Harnessing Intellectual Property Rights for Development Objectives**

*The Double Role of IPRs in theContext of Facilitating MDGs Nos. 1 and 6*

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Cover image: Mr Mohamed Budarhaman. Vegetable seed merchant from Darfur in Konjo - Konjo market Juba, South Sudan selling commercially imported and locally produced vegetable seed (january 2009). Photo: Niels Louwaars.

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## Overall Introduction

### 1. History of the Project

In 2007, the then Minister of Development Cooperation of the Netherlands, Bert Koenders, launched the so-called Schokland Agreement, named after the area of Schokland, a former island in the middle of the Netherlands and in 1995 recognized by UNESCO as a World Heritage Site. The Minister did do so in order to stimulate companies, NGOs, individuals – in short, everybody with a possible interest in development issues – to do their utmost to help realize the UN Millennium Development Goals (MDGs). In reaction to the initiative, a number of people with a background in universities, ministries and platforms with links to international education and research decided to join efforts, leading to the establishment of the '*Platform MDG-Profs*'.[1] As a first step, the Platform developed a plan to make better use of Dutch research institutions and higher education for the benefit of realizing the MDGs. The second step was to develop a large research project on the topic of 'intellectual property rights and development'. The Platform felt that the capacity to open up, generate, share, and use knowledge is an important prerequisite for worldwide development, while intellectual property rights (IPRs) play a central, but also double, role in the management and sharing of knowledge in innovation systems: one the one hand, they are meant to protect knowledge, to stimulate investments in innovation and to support R&D following inventions. On the other hand, they might as well reduce use of technological innovations forthcoming through IPR protected knowledge, because commercialization of knowledge impedes innovation by and for societies that, for instance, cannot provide a (legal) framework to effectively manage IPRs or that cannot promise financial returns. Thus, it was felt by the Platform that poorly developed IPR management hinders equal research partnerships between the South and the North, and often results in a reticent or one-dimensional Northern investment policy and unnecessary delays in the realization of some of the MDGs. This double side of IPRs – also to be labelled in terms like protecting legitimate economic interests *versus* (or alongside) the need to contribute to worldwide development from the perspective of sharing *global public goods*, to which also knowledge is often said to belong – inspired the initiators to set up the present project.

In 2008, the Platform was offered funding by the Ministry of Foreign Affairs and NWO-WOTRO, the division for scientific research on development issues of the Netherlands Organisation of Scientific Research (NWO).

### 2. Contributors to the Project and Acknowledgements

The project has been carried out by a large team of people, in various roles and with a variety of backgrounds relevant to the project. Nine people have acted as researchers, their names being mentioned on the cover of the present book and repeated here in alphabetical order: Julian Barungi (Uganda); Sibongile Gumbi (South Africa); Bram De Jonge (the Netherlands);

[1] See for its history and mandate: <http://www.vsnu.nl/Focus-areas/International-policy/Development-cooperation/Platform-MDG-Profs.htm>. The Platform is now called: Knowledge Forum for Development. The Platform is chaired by Prof. Martin Kropff, Rector Magnificus of Wageningen University, and is financially supported by NWO-WOTRO.

Niels Louwaars (the Netherlands); Bernard Maister (South Africa); Grant Napier (South Africa); Tobias Rinke de Wit (the Netherlands), Godber Tumushabe (Uganda); and Caspar van Woensel (the Netherlands). More information on each of them can be found in the List of Contributors.

The project could not have been carried out without the knowledge and the diversity of practical experiences of a group of experts in the field of intellectual property rights, together being the 'Steering Committee': Victoria Henson-Apollonio, former manager Central Advisory Service on Intellectual Property, Rome; Ruth Okediji, Nigeria, Professor of International Intellectual Property Law, University of Minnesota; Peter Munyi, IP Lawyer, Nairobi; William New, Director and Editor-in-Chief, *Intellectual PropertyWatch*, Geneva; Geertrui van Overwalle, Professor of Intellectual Property Law, Universities of Leuven and Tilburg; Michael S. Pepper, Professor in Health Sciences, Pretoria (had to step aside halfway); Orlando de Ponti, President of the International Seed Federation; and Rosemary Ann Wolson, Professor, Intellectual Property & Technology Transfer, Council for Scientific & Industrial Research, Pretoria. The Steering Committee members played a major role at all stages of the project. All of them attended two plenary meetings to discuss the set-up and the interim findings, while they delivered numerous contributions to the fine-tuning of the end-results. William New also co-edited the final report.

As will become clear below (Par. 3.3. especially), the project consisted of three sub-projects. While the Law School of Tilburg University served as the 'home base' for the project as a whole, as well as for the first sub-project, Wageningen University hosted the second sub-project, while the University of Amsterdam in cooperation with the Foundation PharmAccess hosted the third sub-project. Apart from the people already mentioned, the projects have profited greatly from the input by Julian Kinderlerer, University of Cape Town (sub-projects 1 and 2), while Wendy Stevens, Wits University, South Africa (sub-project 3) and Nico Schrijver as well as Dirk Visser, both Leiden University, the Netherlands, acted as co-readers of specific parts of the report of sub-project 1.

As said, the project had Tilburg University as its home base, but Bram De Jonge and Niels Louwaars, both Wageningen University, and Tobias Rinke de Wit, University of Amsterdam, Center for Poverty-related Communicable Diseases (currently: the Amsterdam Institute for Global Health and Development) and the Foundation PharmAccess International, played an important role as co-coordinators and 'sparring partners'.

## 3. The Project Itself

### 3.1 Introduction

The project focuses on one cumbersome aspect of globalization: the relationship between the international system for the protection of intellectual property and the achievement of the development objectives as formulated the MDGs, in particular MDG 1 ("Eradicate extreme hunger and poverty", target 1c: "Reduce by half the proportion of people who suffer from hunger"); and MDG 6 ("Combat HIV/AIDS, Malaria and other diseases", target 6b: "Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it."). While intellectual property rights play a central role in the management and sharing of knowledge in innovation systems, the assumption of the project is that understanding both the enabling

and limiting factors of such rights in improving access to knowledge and technology for those who can most benefit from it, is of key importance for the realization of the MDGs.

The project aims at understanding the role of intellectual property rights in relation to development. Its purpose is to strengthen the awareness, capacity, and knowledge of scientists, research organizations, and governments in the "South" and the "North" with regard to international and national strategies and attitudes in the field of IP and development. In this way, this projects aims to contribute to the development of sustainable scientific cooperation relationships between "North" and "South" and to the realization of MDGs Nos. 1 and 6. Due to the need to limit the research, this project will focus on two Sub-Saharan African countries (Uganda and South Africa) and the Netherlands. The project thus is situated on the interface between serving the direct (economic) interests of research centres and institutions in the "North" as well as the "South" and the need to contribute to the *global public good*.

### 3.2 Research Questions

The central question of the project is the following: What is the role of intellectual property rights (IPRs) in the management and sharing of knowledge for development, in particular, the achievement of the MDGs 1 and 6?

This central question builds upon 'a web' of four sub-questions. In order to obtain a balanced view of the role of IPRs in the context of the enhancement of the MDGs, it is not only relevant to find out what possible obstacles are created by IPRs in the context of the realization of development objectives (sub-question 1), but also to get a clear picture of best practices or positive experiences with using IPRs to deal with access to knowledge and technology (sub-question 2). Whereas the first two sub-questions define the (negative and positive) role of IPRs in the realization of MDGs, the other two sub-questions concern the way forward. How can the possibly negative relationship between IPRs and the achievement of the MDGs be repaired (sub-question 3)? And in what way can the results of the present project be used by the variety of relevant actors: practical recommendations (sub-question 4)?

These research questions are addressed by three interlinked sub-projects (placed in Parts I, II and III of this report), each covering different disciplines and applying a different method to establishing the relationship between IPRs and the achievement of the MDGs. In Part IV, the conclusions and recommendations of the three sub-projects, are brought together and analyzed in order to obtain a nuanced answer on the central research question (also see Par. 3.4 on Methodology).

### 3.3 Structure of the Report; Description of the Sub-Projects

Part I of this report contains the findings of sub-project 1: *Trade vs. Development: the International Intellectual Property Rights' Regime and the UN Millennium Development Goals*. This project provides the background to and a discussion of the current policy and legal debate taking place in governments, universities and international organizations on the impact of the international intellectual property rights' system on the realization of development objectives. It outlines the development and history of IPR law in general and frames the obstacles to development created by IPR law and the application of the international IPR regime to developing countries. Most attention is given to the Agreement

on Trade-Related Aspects of Intellectual Property Rights (TRIPS), as the dominant international IPR agreement in the modern era, and on patents as the most significant of the IPR instruments in this context. Other issues specifically covered include the need to have the domestic capacity to build an IPR system, the 'power differential' between developed and developing countries and the question how this differential impacts negotiations on and enforcement of existing IPR law. This is followed by discussion of the 'post-TRIPS world', e.g., the renewed importance of bilateral trade agreements.

Part II of the report consists of the findings of sub-project 2: *Agricultural Seeds That Reduce Hunger and Poverty – Policies, Perceptions and Practices in Intellectual Property Rights*. This project examines the relationship between IPRs, agriculture, and MDG 1c (see above). The study analyzes the roles that different IPR policies and practices play in agricultural research and development trajectories in both a developed context (in particular the Netherlands) and a developing context (in particular Uganda). Ultimately, the aim of the sub-project is: 1) to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries; and 2) to contribute to the realization of IPR strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and that increase food security in developing countries. The research focuses on the full chain of actors involved, from ministries in the North and the South and research centres in both worlds, to the local end-users and producers of relevant IPR knowledge.

Part III of this report consists of the outcome of sub-project 3: *Affordable HIV Drug Resistance Test for Africa (ART-A) Intellectual Property***.** This study focuses on the relationship between IPRs, the medical diagnostics sector, and MDG 6b (see above). The study examines a European and African research consortium called the Affordable Resistance Test for Africa (ART-A: http://www.arta-africa.org/) that was established to develop technologies for affordable HIV drug resistance testing in Africa. The end goal of the study is to ensure that products and services developed by the ART-A research consortium can be successfully produced and effectively used in combatting the HIV and AIDS epidemics. For that purpose, the study describes the IPR environment of the ART-A research consortium and explores suitable IP protection models that could be used by public-private partnerships developing medical diagnostic technologies to facilitate broader access to diagnostic testing in Africa.

Part IV contains the synthesis, concluding remarks and recommendations of this research project. The synthesis and concluding remarks are based on a comparison and analysis of the conclusions formulated at the level of the sub-projects (Parts I, II, and III of the report). The last part of Part IV contains practical recommendations based on the outcomes and recommendations of the individual sub-reports and on the synthesis and concluding remarks. These recommendations are directed towards policy makers at the global, regional and national level, funding organizations, and universities and (other) research institutes.

### 3.4 Methodology; Complementarity of the Sub-Projects

Each of the sub-projects covers different disciplines, has a different focus and applies a different method to establish the relationship between IPRs and the achievement of the MDGs. They have been chosen this way in order to be complementary to one another. However, they also have commonalities: the binding element between the three sub-projects

consists of a framework of questions, i.e., the above-mentioned core question together with the 'web' of four sub-questions. In the end, all three projects do search, each in its own way and applying its own method, for answers to the same set of questions. The outcomes of the individual sub-projects can be found at the end of each sub-report, while in Part IV the outcomes of the three sub-projects are linked.

When perceived together, the three sub-projects reflect a rather unique combination of researchers, disciplines and entrances to the debate on 'IPRs and development': a combination of North-South research partnerships, with multi-, inter- and trans-disciplinary cooperation between technological expertise in the field of agriculture/food and medicines and expertise in the field of international as well as national regulations and legislation on IPR law. This combination adds several dimensions to the outcomes of the three sub-project reports and offers a number of opportunities for comparison and analysis.

For instance, as already visible from the above descriptions, the three sub-projects approach the questions from a different angle: while sub-project 1 discusses the general theoretical and legal background that bears on the role of the current international IP regime in achieving the MDGs 1 and 6, the two case-studies shed light on the implications of IPRs for knowledge development and transfer in the field agriculture (MDG 1) and medical devices (MDG 6). Further to that, the first sub-project approaches the field of international IPRs with an overall 'helicopter' view, while the second sub-project provides a macro perspective by analyzing the chain of knowledge transfer from Dutch universities and research institutes to smallholder farmers in Uganda, and *vice-versa*. Next to that, the third sub-project provides a micro perspective on the relevant research questions by zooming in on the search for suitable IP protection models in the context of the ART-A consortium which aims to develop technologies for affordable HIV drug resistance testing in Africa.

Taking the findings together, it will become clear that due to the set-up of the project and the way the sub-projects have been carried out, conclusions can and will be drawn on a variety of levels. To conclude this introductory Part, we would like to mention three such levels and accompanying perspectives:

- The geographical perspective: a) the local level: farmers in Uganda, b) the national level: governments in the Netherlands, Uganda, and South Africa; c) the regional level: the Organisation Africaine de la Propriété Intellectuelle (OAPI), the African Regional Intellectual Property Organisation (ARIPO) and the EU (to some extent); d) the global level: the WTO, the International Union for the Protection of New Varieties of Plants (UPOV), and the World Intellectual Property Organization (WIPO).
- The actors' perspective: a) local farmers and breeders in Uganda, researchers and staff of medical laboratories in Uganda and South Africa; other private sector people in the South and the North, applying the findings analogously; b) research institutes and universities in the Netherlands, Uganda and South Africa; c) governments in the Netherlands, Uganda, and South-Africa.
- The perspective of the complementary approaches, chosen by and for each of the sub-projects: a) an overall approach, providing insights in historical developments and present international debates on the relation between IPRs and MDGs (sub-project 1), b) a chain-analysis conducted on IPRs in the agricultural context (sub-project 2) and c) a micro-analysis of a concrete model in the medical context (sub-project 3).

In conclusion: it has been an intense project, to be conducted in two years overall, with 1.5 years for the actual research only. However, the cooperation of totally different disciplines indicates that it would and actually will be very useful to establish more such coalitions, addressing North-South topics 'that really matter'. The confrontation between disciplines and the inclusion of the actors' perspective on a variety of levels has lead to insights that would not have been reached should the problem under scrutiny in this report have been defined in a mono-disciplinary and purely scientific way only. It has become clear again that research which finds its inspiration in practical issues can lead to innovate scientific insights. We hope the readers of this report feel as inspired as we do.

Willem van Genugten
Anna Meijknecht
Tilburg, 15 July 2011

## Acronyms

| | |
|---|---|
| AATF | African Agricultural Technology Foundation |
| ABL | Advanced Biological Laboratories |
| AIDS | Acquired Immunodeficiency Syndrome |
| AGRA | Alliance for a Green Revolution in Africa |
| AGT | Agro-Genetic Technologies Limited |
| AMC | Amsterdam Medical Centre |
| ANDi | African Network for Drugs and Diagnostics Innovation |
| ARIPO | African Regional Intellectual Property Organisation |
| ART-A | Affordable Resistance Test for Africa |
| ARV | Antiretroviral |
| ASARECA | Association for Strengthening Agricultural Research in Eastern and Central Africa |
| ASR | Analyte Specific Reagent |
| AUC | African Union Commission |
| AUTM | Association of University Technology Managers |
| AVRDC | World Vegetable Centre |
| AWT | Advisory Council for Science and Technology Policy (Netherlands) |
| BEE | Black Economic Empowerment |
| CAADP | Comprehensive Africa Agriculture Development Programme |
| CBD | Convention on Biological Diversity |
| CDA | Confidential Disclosure Agreement |
| CDC | Center for Disease Control and Prevention |
| CDIP | Committee on Development and Intellectual Property |
| CFC | Common Fund for Commodities |
| CGIAR | Consultative Group on International Agricultural Research |
| CIAT | International Centre for Tropical Agriculture |
| CIMBAA | Collaboration on Insect Management for Brassicas in Asia and Africa |
| CIMMYT | International Maize and Wheat Improvement Centre |
| CIP | International Potato Centre |
| CIPIH | Commission on Intellectual Property Rights, Innovation and Public Health |
| CIPRO | Companies and Intellectual Property Registration Office |
| CMH | Commission on Macroeconomics and Health (WHO) |
| CPA | Africa's Science and Technology Consolidated Plan of Action |
| CPA | Copyright and Patent Agreement |
| CPCD | Center for Poverty Related Communicable Diseases |
| CRP- Santé | Centre de Recherche Publique de la Santé |
| DDPSC | Donald Danforth Plant Science Centre |
| DFID | United Kingdom Department for International Development |
| DGIS | Netherlands Ministry of Development Cooperation |
| DMCA | Digital Millennium Copyright Act |
| DNA | Deoxyribonucleic Acid |

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|---|---|
| DuRPh | Durable Resistance against Phytophthora |
| EC | European Commission |
| ECOWAS | Economic Community Of West African States |
| EL&I | Netherlands Ministry for Economy Agriculture and Innovation |
| EPAs | Economic Partnership Agreements |
| EPO | European Patent Office |
| EU | European Union |
| EZ | (former) Netherlands Ministry of Economic Affairs (now part of EL&I) |
| FAO | Food and Agriculture Organisation |
| FDA | Food and Drugs Administration (US) |
| FDC | Fixed-Dose Combination |
| FDI | Foreign Direct Investment |
| FTAs | Free Trade Agreements |
| FTO | Freedom to Operate |
| GATB | Global Alliance for TB Drugs |
| GATT | General Agreement on Tariffs and Trade |
| GAVI | Global Alliance Vaccine Initiative |
| GBS | Global Bio-Collecting Society |
| GFATM | Global Fund to Fight AIDS, Tuberculosis and Malaria |
| GI | Geographical Indications |
| GM | Genetic Modification |
| GMO | Genetically Modified Organism |
| GMP | Good Manufacturing Practice |
| GNU | GNU's Not Unix |
| GPL | General Public License |
| GSK | GlaxoSmithKline Plc |
| HIV | Human Immunodeficiency Virus |
| HIVDR | Human Immunodeficiency Virus Drug Resistance |
| HIV VL | Human Immunodeficiency Virus Viral Load |
| IAVI | International Aids Vaccine Initiative |
| ICCPR | International Covenant on Civil and Political Rights |
| ICTSD | International Centre for Trade and Sustainable Development |
| IFAD | International Fund for Agricultural Development |
| IFC | International Finance Corporation (World Bank Group) |
| IGWG | Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (WHO) |
| IITA | International Institute for Tropical Agriculture |
| IITC | Inter-Institutional Trade Committee |
| IMPACT | International Medical Product Anti-Counterfeit Taskforce |
| IP | Intellectual Property |
| IPC | International Patent Classification |
| IPFA | International Project Finance Association |
| IPGRI | International Plant Genetic Resources Institute |
| IPRs | Intellectual Property Rights |
| IPSF | Intellectual Property Support Fund |

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|---|---|
| ITPGRFA | International Treaty on Plant Genetic Resources for Food and Agriculture |
| IVD | *In Vitro* Diagnostic |
| IUO | Investigational Use Only |
| IUPGR | International Undertaking on Plant Genetic Resources |
| JCRC | Joint Clinical Research Centre |
| JITAP | Joint Integrated Technical Assistance Programme |
| KNAW | Royal Netherlands Academy of Arts and Science |
| LDC | Least Developed Country |
| LDT | Laboratory Developed Test |
| LNV | (former) Netherlands Ministry of Agriculture, Nature and Food quality (now part of EL&I) |
| MCC | Medicines Control Council |
| MDG | Millennium Development Goal |
| MOU | Memorandum of Understanding |
| MPEP | Manual of Patent Examining Procedure |
| MSF | Médecins sans Frontières |
| MTA | Material Transfer Agreements |
| MTTI | Ministry of Trade, Tourism and Industry |
| MVI | Malaria Vaccine Initiative |
| NACCAP | Netherlands-African Partnership for Capacity Development and Clinical Interventions against Poverty-Related Diseases |
| NaCRRI | National Crops Resources Research Institute |
| NANEC | National Network of Cassava workers |
| NARO | National Agricultural Research Organisation |
| NGI | Netherlands Genomics Initiative |
| NGO | Non-Governmental Organisation |
| NEPAD | New Partnership for Africa's Development |
| NIH | National Institutes of Health (US) |
| NIPMO | National Intellectual Property Management Office |
| NRM | Natural Resource Management |
| NWO | Netherlands Organisation for Scientific Research |
| OAPI | Organisation Africaine de la Propriété Intellectuelle |
| OAU | Organisation of African Unity |
| OECD | Organisation for Economic Cooperation and Development |
| OC&W | Netherlands Ministry for Education, Culture and Science |
| OIN | Open Invention Network |
| OSDD | Open Source Drug Discovery |
| PASER | PharmAccess African Studies to Evaluate Resistance |
| PBR | Plant Breeders' Rights |
| PCDA | Provisional Committee on Proposals Related to a WIPO Development Agenda |
| PCR | Polymerase Chain Reaction |
| PCT | Patent Cooperation Treaty |
| PEPFAR | US President's Emergency Plan for AIDS Relief |
| R&D | Research and Development |
| PIC | Prior Informed Consent |

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|---|---|
| PIIPA | Public Interest Intellectual Property Advisors |
| PIPRA | Public Intellectual Property Resource for Agriculture |
| PPPs | Public-Private Partnerships |
| PRAPACE | Regional Potato and Sweet Potato Improvement Network in Eastern and Central Africa |
| PTAs | Preferential Trade Agreements |
| PVP | Plant Variety Protection |
| R&D | Research and Development |
| RUO | Research Use Only |
| SAHPRA | South African Health Products Regulatory Authority |
| SANAS | South African National Accreditation Service |
| SAP | Structural Adjustment Programme |
| SME | Small and Medium-sized Enterprise |
| SNP | Single Nucleotide Polymorphisms |
| STD | Sexually Transmitted Disease |
| STI | Sexually Transmitted Infection |
| STW | Technology Foundation (Netherlands) |
| TB | Tuberculosis |
| TDR | WHO Special Programme for Research and Training in Tropical Diseases |
| TK | Traditional Knowledge |
| TKDL | Traditional Knowledge Digital Library |
| TRALAC | Trade Law Centre for Southern Africa |
| TRIPS | Agreement on Trade-Related Aspects of Intellectual Property Rights |
| TTI-GG | Technological Top Institute – Green Genetics (Netherlands) |
| TT(O) | Technology Transfer (Office) |
| UBOS | Uganda Bureau of Statistics |
| ULRC | Uganda Law Reform Commission |
| UMCU | University Medical Centre Utrecht |
| UN | United Nations |
| UNAIDS | Joint United Nations Programme on HIV/AIDS |
| UNBS | Uganda National Bureau of Standards |
| UNCST | Uganda National Council for Science and Technology |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| UNESCO | United Nations Educational, Scientific and Cultural Organisation |
| UNIDO | United Nations Industrial Development Organisation |
| UNSSPA | Uganda National Seed Potato Producers' Association |
| UPOV | International Union for the Protection of New Varieties of Plants |
| URSB | Uganda Registration Services Bureau |
| US | United States of America |
| USAID | United States Agency for International Development |
| USDA | United States Department of Agriculture |
| USPTO | United States Patent and Trademark Office |
| VCA | Visitors Confidentiality Agreement |
| VSNU | Association of Universities in the Netherlands |

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| WCO | World Customs Organization |
| WHC | Wits Health Consortium (Pty) Ltd. |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organisation |
| WITS | University of the Witwatersrand |
| WOTRO | Science for Global Development Programme (of NWO) |
| WRR | Dutch the Scientific Council for Government Policies |
| WTO | World Trade Organisation |
| WUR | Wageningen University and Research Centre |

# PART I

## TRADE VS. DEVELOPMENT: THE INTERNATIONAL INTELLECTUAL PROPERTY RIGHTS REGIME AND THE UN MILLENNIUM DEVELOPMENT GOALS

*An Introduction to the Problems with International IPR Obligations in the Light of Development Priorities in Sub-Saharan Africa*

**By**

**Bernard Maister**
**and**
**Caspar van Woensel**

## Contents

## SUMMARY OF CONCLUSIONS

In summary, Part I concludes that:

(1) The controversial issue of access to medicines and seeds evolve primarily around *patents*, but a country's *infrastructure* is at least as important;
(2) The negotiation history of TRIPS proves that international IPRs are the result of a drive by governments and industries in the "North";
(3) The implementation of TRIPS and TRIPS-plus obligations in developing countries shows that those obligations are a burden to the "South" in terms of capacity and cost;
(4) IPRs are designed to serve the purposes of trade, facilitating innovation and/or fostering economic growth, not development;
(5) The international IPR system, like any legal system, can only be successfully utilized for the purpose for which it was designed;
(6) While the potential for use and benefit of implemented IPR systems in developing countries in general is unproven, this potential is so far only evidenced in the presence of manufacturing capability, skilled human resources, market diversification, and technological capability – excluding most parts of Sub-Saharan Africa;
(7) Thus, in the Sub-Saharan region TRIPS-compliant national IPR systems might benefit foreign rights holders only, while not doing much for local use, which the mere presence of a (patent) system does not create;
(8) An understanding of the mechanisms of innovation and imitation of technology and methods in specific sectors in developing countries can help those countries to determine effective IPR policies;
(9) While Sub-Saharan Africa has some clear common concerns, it must be acknowledged that the 47 countries in that region have individual characteristics and circumstances, necessitating specific analysis and policies;
(10) Patents may hamper MDGs as patents mean control – of the market price, the invention, and related R&D and data – and there is a general lack of coherence of development goals (including the MDGs) and IPR goals.

# CHAPTER 1 OBJECTIVE, SCOPE, AND CONCEPTS

## 1.1 About This Report

### 1.1.1 Objective

This report provides the background to and a discussion of the current policy and legal debate taking place in governments, universities and international organizations on the impact of the international intellectual property rights (IPRs) system with particular reference to its impact on achieving the Millennium Development Goals (MDGs).[1] This report is accompanied by two separate case studies, one involving agriculture (see PART II), the other diagnostics-pharmaceuticals (see PART III).[2] The two case studies focus on specific Sub-Saharan Africa countries, in particular South Africa and Uganda. Hereafter, "this report" will be taken to specifically mean the current analysis in Chapters 1-6 of PART I.

This report outlines the development and history of IPR law in general. More specifically it frames the obstacles to development created by IPR law and the application of the international IPR regime to developing countries. Most attention must be given to the World Trade Organization "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPS), as arguably the dominant international IPR agreement in the modern era.

The report focuses on patents as the most significant of the IPRs in this context. Other issues specifically covered include the need to have the domestic capacity to build an IPR system, the "power differential" between developed and developing countries and how this differential impacts negotiation and enforcement and the "post-TRIPS world" – e.g., the importance of bilateral trade agreements.

This report, by specifying sectors, countries and regions, focuses on the public health and agricultural sectors in Sub-Saharan Africa where many countries struggle to meet the United Nations' Millennium Development Goals.[3]

### 1.1.2 Scope

While an extensive literature is available covering various aspects of IPRs, development and international trade, the focus of this report, to provide a concise overview of the IPR system and how it impacts achieving the MDGs, is unique. The difficulty of such a report is not what to include but rather what to exclude. The authors, having reviewed the extensive literature available, chose to produce a report based upon standard references while also including some of the more provocative writings in the field.[4] While the primary reader is presumed to

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1 Sources have been added to this report until 15 April, 2011.

2 See in detail: project introduction and separate reports.

3 As shown by Odagiri *et. al* (ed.) 2010, p. 421.

4 A review of the authors' Reference List will illustrate this. This report draws on the following scholarly literature in particular: (1) Gana 1995, Drahos & Mayne (eds.) 2002, Drahos 2002a, Okediji 2003a, Okediji 2003b, Gervais (ed.) 2007, Li & Correa (eds.) 2009, Deere 2009, De Beer (ed.) 2009, Weinstock Netanel (ed.) 2009, Van Overwalle (ed.) 2009, Stiglitz 2010, Wong & Dutfield (eds.) 2011, on the nature and goals of IPRs, the international IPR framework, and development perspectives to IPRs; (2) Lee 2006, Heath & Kamperman Sanders (eds.) 2007, Hoekman & Kostecki 2009, and Manger 2009, on the global trading system and (bilateral, regional) trade agreements, and development perspectives to the trading system; (3) Pogge 2008,

be Dutch government officials involved in legal and policy matters with regard to IPRs, trade and development, it is believed that the report will be of value to others interested in the field.

An important part of this report covers the relatively new and rapidly changing field linking IPRs and socio-economic development. While the authors have included a discussion of this area, it is still being developed. For example, most relevant publications, such as *Wong & Dutfield (eds.) 2011*, only became available in the course of the project.

While this report does not purport to be a detailed review, the reader should be able to quickly gain a (practical) understanding of national and international IPR law and how it creates obstacles affecting the MDGs in Sub-Saharan Africa particularly in the fields of public health and agriculture. In addition to providing a background to the topic, the authors have included specific recommendations to overcome the obstacles detailed.

### 1.1.3 "Trade vs. Development"

Developing countries have struggled with the implementation of the international IPR system. To be compliant with international requirements necessitates either setting up *de novo* or modifying current administrative and judicial systems. Such efforts may involve both legislative and regulatory efforts including the training of legislators, administrators, lawyers and judges. However, implementing international standards of intellectual property rights often clash with their development needs. An example is the impact of IPRs on access to medicines and seeds, critical to combating emergencies in public health and food security respectively.

Combining IPRs with trade management in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), discussed in detail below, has neither fully met the expectations of the developed countries that promoted this approach nor that of the developing states that were required to implement the international IPR framework. The result has been dissatisfaction on both sides, and an ongoing debate to decide on an approach that nurtures international trade, including IPR protection, and promotes development in African countries.

### 1.1.4 Set-up of This Report (Chapters 1-6)

This report is divided into four main sections, each a separate Chapter. Chapter 1 introduces the focus of this report, including terms and concepts such as the MDGs, intellectual property rights, and development cooperation. The next Chapters describe the obstacles, divided into those deriving from the nature and goal of IPRs (Chapter 2), those produced by the international IPR system (Chapter 3), those related to infrastructure (Chapter 4) and, finally, obstacles originating from the relationship between developed and developing countries – the "power differential" (Chapter 5). Chapter 6 summarizes the conclusions and details the recommendations.

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Easterly 2008, and Peet & Hartwick 2009, on development. These selected sources have been particularly helpful in providing insight into the many dimensions of the subject of this report and are at the basis of sections throughout this report. In addition, *IP Handbook* 2007 is mentioned, a freely downloadable, extensive collection of case-studies and best practices on IPR (management) in developing countries, although few specifically on Africa.

## 1.2 The Focus of This Report

### 1.2.1 Developing Countries

In this report, the term "developing countries" refers to countries, mostly African and Asian, that are in the process of achieving one or more MDGs. The countries of Sub-Saharan Africa are all considered "developing" (see para. 1.2.2, 1.2.3) The technologically and industrially more advanced among the developing countries are often identified as "catch-up", "fast-follower" or "frontier" countries. Another group, the so-called "least developed countries" (LDCs), are considered to lack a functioning economy. Because the issues facing both groups are similar, the authors have treated the two groups together.[5]

Developing countries are frequently called the "South" while developed countries are designated the "North". Although not chosen for its sophistication or for its geographical accuracy, the "North-South" distinction has become popular in circles over development cooperation (see para. 1.2.11) because it is convenient. Because of this ease of use, the authors have chosen to follow this format.

### 1.2.2 Sub-Saharan Africa

This report focuses on Sub-Saharan Africa, a region viewed by the United Nations as troublesome in terms of extreme poverty. Sub-Saharan Africa consists of currently 47 countries, some of which are actually Intra-Saharan.[6] The Sub-Saharan region is at the center of international aid and development efforts, including efforts by the Netherlands. The almost 50 different Sub-Saharan countries, while differing vastly in size, population and economy, nevertheless face similar grave problems on a range of issues - governance and finances, conflict, economy and growth, food security, health, and climate. Even South Africa and Nigeria, with 24,3 % of the population together making up as much as 45,6 % of Sub-Saharan Africa's GDP (2009),[7] both face MDG challenges. While overall regional progress has reportedly been slow and uneven, large gains have been reported in areas such as education (see table Sub-Saharan Africa development indicators).[8]

In this report, South Africa and Uganda will be used as primary examples of developing and least developed countries respectively.

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5 For data on developing countries reference is made here to the Organisation for Economic Co-operation and Development (OECD), for example lists of developing countries and official development assistance (ODA): <http://www.oecd.org/topic/0,3699,en_2649_37413_1_1_1_1_37413,00.html> (accessed on 1 July 2011).

6 Source < http://geography.about.com/od/lists/a/officiallist.htm > (accessed on 1 July 2011). The region consists of the following countries: Angola, Benin, Botswana, Burkina Faso, Burundi, Cameroon, Cape Verde, Central African Republic, Chad, Comoros, Republic of the Congo, Democratic Republic of the Congo, Cote d'Ivoire, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gabon, The Gambia, Ghana, Guinea, Guinea-Bissau, Kenya, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Sao Tome and Principe, Senegal, Seychelles, Sierra Leone, South Africa, Sudan, Swaziland, Tanzania, Togo, Uganda, Zambia, Zimbabwe.

7 According to Africa Development Indicators 2009, as published by the World Bank's Africa Region.

8 Source < http://go.worldbank.org/oKBY1V9YT0 > and MDG Report 2010 (accessed on 1 July 2011).

| Sub-Saharan Africa development indicators[9] | Yr 2009 |
|---|---|
| Population, total (millions) | 839.6 |
| Population growth (annual %) | 2.5 |
| GDP (current US$) (billions) | 946.1 |
| GDP per capita (current US$) | 1,127 |
| GDP growth (annual %) | 1.7 |
| Life expectancy at birth, total (years) | 52.1 |
| Mortality rate, infant (per 1,000 live births) | 80.8 |
| Literacy rate, youth female (% of females ages 15-24) | 67.0 |
| Prevalence of HIV, total (% of population ages 15-49) | 5.0 |

### 1.2.3 Development

The term "development" has multiple meanings, depending on its context. Studies on developing countries, including those dedicated to an aspect of the MDGs, rarely define development or clarify precisely how the term is being used. For the purpose of this report, the following three definitions or views of development are provided.

"The first [definition of development] is historical and long term and arguably relatively value free – 'development' as a process of change … The second is policy related and evaluative or indicator led, is based on value judgments, and has short- to medium-term time horizons – development as the MDGs, for example. The third is post-modernist, drawing attention to the ethnocentric and ideologically loaded Western conceptions of 'development' and raising the possibilities of alternative conceptions."[10]

Consistent with the first definition, development has been defined as an enduring process of organizational change that requires a country to go through different stages before reaching a condition of institutional sophistication.[11] This process of organizational change is shaped by human, natural and financial resources, available technology and skills, the particulars of government and governance, history and traditions, the success or failure of existing institutions, and distribution of wealth.[12] It is this definition that is helpful in visualizing the gap countries in Sub-Saharan Africa face when trying to meet international infrastructural requirements for their IPR system.[13]

In addition, the authors of this report have used the second policy-related definition considering it most consistent with the role of MDGs. The MDGs (detailed in para. 1.2.4)

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9 Source World Bank, < http://go.worldbank.org/WS9IHREF30 > (accessed on 1 July 2011).

10 Sumner & Tribe 2008, p. 11.

11 Banji & Padmashree 2010, p. 5.

12 Adapted from Banji & Padmashree 2010, p. 5.

13 This issue will be expanded on in Chapter 4. There are many other definitions of development not considered here. *E.g.* Wong & Dutfield (eds.) 2011, pp. 3-4 stress the element of choice – expanding choices people have to lead lives that they value (referencing the United Nations Development Programme, UNDP); see also same source, p. 36.

essentially aim at raising living conditions for people everywhere to the level where "basic needs" are met.[14] What represents the minimum level is explained in the MDGs and their associated targets and indicators.[15]

### 1.2.4 The Millennium Development Goals (MDGs)

In 2000, the "Millennium Declaration" was established within the framework of the United Nations. It promised a "wide-ranging global partnership for development" committed to improving living conditions for people in the poorest countries by the year 2015.[16] The Millennium Declaration maintains that all countries "have a collective responsibility to uphold the principles of human dignity, equality and equity at the global level" (Art. 2). To this end, countries including the Netherlands[17] have agreed to the Millennium Development Goals (MDGs, or Goals), based on and enforceable as "human needs and basic rights".[18] The eight main Goals (for further details see Annex I: *List of official MDG indicators*) are as follows.

Goal 1 Eradicate extreme poverty and hunger
Goal 2 Achieve universal primary education
Goal 3 Promote gender equality and empower women
Goal 4 Reduce child mortality
Goal 5 Improve maternal health
Goal 6 Combat HIV/AIDS, malaria and other diseases
Goal 7 Ensure environmental sustainability
Goal 8 Develop a global partnership for development

The Goals are interrelated and are related to different aspects of extreme poverty.[19] By urging the international community to work together towards a common end – "making sure that human development reaches everyone, everywhere" the MDGs are also an expression of political ideals.[20] With the Millennium Declaration, developed nations have committed to providing support, both direct (e.g. financial) and indirect (e.g., lifting trade barriers). In the long term, global benefits are expected from improved conditions in poor countries through increased trade and stability.

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14 Adapted from Peet & Hartwick 2009, p. 1.

15 This does not mean to say that this kind of methodical approach to development is free of controversy. As Easterly 2008, p. 10 puts it, behind poverty-reduction programs often is the (implicit) view that development is a "kind of engineering problem" like building "a dam or electric plant", whereas development "presents many variables of human behavior".

16 See: <www.un.org/millenniumgoals/ and www.endpoverty2015.org> (accessed on 1 July 2011) . See on the context of the MDGs, among others, Peet & Hartwick 2009, pp. 94-97.

17 See: official document *Kamerbrief inzake basisbrief Ontwikkelingssamenwerken (Bijlage)*, 26 November 2010, published on <rijksoverheid.nl>, outlining the Netherlands' policy for development cooperation as of late 2010, and the previous official policy document Policy Note 2007.

18 MDG Report 2010, p. 3.

19 See < http://www.undp.org/mdg/basics.shtml > and United Nations Development Group report 'Indicators for Monitoring the Millennium Development Goals' (ST/ESA/STAT/SER.F/95), New York: United Nations 2003 (accessed on 1 July 2011) .

20 See < http://www.undp.org/mdg/basics.shtml >(accessed on 1 July 2011).

The remainder of the report will focus on agriculture (MDG 1/food security) and pharmaceuticals and diagnostics (MDG 6/public health).[21] The discussion of IPR obstacles in the following Chapters should be read within the context of the outcomes of the associated case studies on agriculture (see PART II) and pharmaceuticals and diagnostics (see PART III) that complete this report.

### 1.2.5 MDG Concerns Over Food Security, Public Health in Sub-Saharan Africa

In a quantitative assessment of the importance of the MDGs to 26 countries in Sub-Saharan Africa, eradicating hunger and poverty and combating HIV/AIDS proved all-important to the African people (top-3). [22] Living conditions in the Sub-Saharan region are especially concerning because of the high incidence of hunger, drought, disease, joblessness, conflict and overall instability of countries. This African emphasis on putting food security and public health at the forefront is consistent with the United Nations-coordinated MDG efforts.

Although the situation has improved in the past decade, typically countries in Sub-Saharan Africa suffer critical defects such as poorly performing markets and government institutions. Although standards differ from one country to another, many African countries have scarce availability of proper education, training and skills; doctors, hospitals and equipment; and human resources, technology and manufacturing capability.[23] This points to a need for improved African countries' general infrastructures (see para. 1.2.7). This is only partially covered by current MDG efforts, aimed at the eight main Goals (see para. 1.2.4).

In addition, many African countries, as former colonies, share a relatively short history of independence beginning in the 1950's and 1960's. In many cases, their leaders proved to be generally undemocratic often succumbing to nepotism and corruption.[24] African states generally lacked the political and economic stability and self-reliance of other relatively newly-independent states such as Indonesia.

Industrialized South Africa, which is generally an exception in this regard, has yet to meet all MDGs. South Africa's middle class, essential to "carry" development,[25] is growing, but this relative success does not quite change the overall picture. While South Africa has signaled its infrastructure, private sector and macro-economy as strong points, it continues to have significant difficulty providing access to both quality education (considered a way out of low-income jobs) and health care. The lack of accessibility to quality health care, together with the high prevalence of HIV/AIDS in the country, explains why South Africa has failed to completely achieve all MDG targets.[26] But here the news is not all bad: HIV prevalence in South Africa appears to be stabilizing after peaking in the 1990s and early 2000s and now the

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21 See a brief review of MDG efforts in Chapter 5, para. 5.3. For MDG 1 target 3 and MDG 6 targets 1-2 see <http://www.un.org/millenniumgoals/poverty.shtml> and <http://www.un.org/millenniumgoals/aids.shtml> respectively.

22 Robert D. Tortora, 'Sub-Saharan Africans Rank the Millennium Development Goals (MDGs)' (survey 2006), Gallup World Poll 2009, pp. 1-8.

23 The need for improved general infrastructure and the failure to address this problem is discussed in detail below (see para. 1.2.7 and para. 1.2.4).

24 See for example historic description of the region by Calderisi 2007.

25 Phrasing by *The Economist* 2010a, p. 46.

26 UNDP Millennium Development Goals Country Report South Africa 2010, p. 3.

country has the largest Anti-Retroviral Therapy program in the world.[27] The United Nations Development Programme has warned that such hard-fought gains can be lost, and ways to protect existing gains have to be prioritized.[28]

### 1.2.6 Intellectual Property Rights (IPRs)[29]

"Intellectual property rights" (IPRs) can be described as the rights given to people over the creations of their minds.[30] IPRs are legal tools that provide a negative right by serving to deny others the use of those creations unless they obtain permission first (and usually pay royalties) to the rights owner. IPRs include plant breeders' rights, patents, copyrights, trademarks, designs, et cetera that provide the rights' holder with exclusive, but temporary, control of an invention or creation.[31] IPRs give the holder of the right certain legally enforceable options. These include, for example, price-setting, control of distribution and protection against illegal copying of the (intellectual) property.

IPRs are commonly referred to as "intangible" property and often an inseparable part of a product. For example, a "patented" pharmaceutical product consists of both tangible and intangible components, former being the actual pill, the latter the associated IPRs which may include a patent, a trademark and a copyright.[32]

IPRs are an extensive family of rights, each member different but related and with a specific legal regime. They are generally considered "private rights" and are both territory- and time-limited. Regarding the territorial aspect, IPRs are only valid within country granting them where they are subject to the local (national) rules for the protection and enforcement of the right. The time-limitation involves the entry of the protected invention into the public domain after the expiration of the legal protection. IPRs may require registration, such as is the case with patents, but may be "automatic," as in the case of copyrights. While these rules are generally true in Europe or the United States, for instance, specific national IPRs are not universal rights. In fact, there is a common misconception in this regard and "universal"

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27 UNDP Millennium Development Goals Country Report South Africa 2010, p. 76.

28 Beyond Midpoint 2010.

29 The reader is reminded that the authors' goal has been to provide an all-encompassing review of the topic but, as described above, have had to sacrifice some detail to achieve this. The reader must be aware that the precise definitions and legal criteria of individual IPRs differ in detail between, for example, Europe and the United States. However the concepts described in this report are generally consistent between countries.

30 Definition by World Trade Organization (WTO),
source < http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm >(accessed on 1 July 2011).

31 There are many comprehensive textbooks on IPRs. Useful examples include: Bently & Sherman 2008; Ricketson & Creswell 2006; Maskus 2000. These sources are already outdated to some extent but hold valuable insights. Other useful textbooks discussing IPRs in international contexts are Dutfield & Suthersanen 2008 and Cornish & Llewelyn 2007. These titles are a random selection given the wealth of sources available. IPR law and policy has national, European and international dimensions and evolves and expands continuously.

32 Depending on the country in question, there may be patents on the structure, use and method of manufacture of the drug, trademark protection on the name of the drug and the name of the manufacturing company, and copyright protection on the associated package insert.

patents, copyrights or other intellectual property rights do not exist, because of the territorial limitation of IPRs.[33]

An important commercial practice commonly associated with managing IPRs is the licensing of IPRs whereby a third party obtains various rights such as the right to reproduce, manufacture and/or sell the products subject to the conditions in the licensing contract. However, as noted above, these rights are time-limited and why IPRs can best be considered as temporary monopoly rights. Historically, the central issue facing IPR law has been how to balance this "monopoly" against the interests of fellow competitors and others in society that have a desire to use or even improve the new, but protected invention or creation.

As may be appreciated, IPRs are not static and, in order to continue to fulfill their underlying goal of rewarding new invention must keep up with technological developments. To achieve this requires IPRs to adapt through legislative and judicial changes in response to trends in those fields considered patentable subject matter.[34] This explains why IPRs cannot be a closed system. Instead, IPRs must adapt to new developments, including the creation of new IPRs or related rights, such as in the case of internet domain names. It also explains that IPRs cannot be a static system either.

IPRs in one form or another date back at least five hundred years.[35] In the modern era, they have expanded to cover areas such as the biological sciences including, for example, genes and living entities. Although, as indicated above, exactly what subject matter is considered "patentable" depends on the country concerned. Even in areas such as mechanical engineering, many technological advances that require protection did not even exist a few years ago. As a consequence, developing and developed countries need to constantly re-evaluate, and if necessary update, their domestic intellectual property legislation. The laws and regulations defining the elements of patentability – for example, "novelty", "patentable" subject matter – have "to be constantly modified, to keep them updated with changes in, say, technology and institutional arrangements."[36]

Besides its dynamic nature, it must also be noted that a national IPR system cannot exist in isolation but rather must be integrated with other areas of the law and policy. An important example is competition law – encompassing such legal areas as unfair competition (or "anti-trust" regulations as it is called in the United States) – which has to work together with an IPR regime to produce adequate regulation of the market. Often developing countries including those in Sub-Saharan Africa lack not only an established modern IPR system but also functioning competition law systems. This will be briefly discussed in Chapter 4 of this report. The nature and goal of IPRs will be discussed in more detail in Chapter 2.

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33 Thus, a product is only protected in the country or countries in which patent rights have been granted. A product patented in the US only, may be freely used, sold or copied, for example, in countries where patent rights have either not been applied for or granted.

34 As discussed elsewhere, what is considered "patentable", and the patentable criteria, may be different from country to country.

35 For a detailed history of IPRs is referred to any of the standard texts on the topic, see references in para. 1.1.3.

36 Stiglitz 2010, p. 239. In great detail on this topic, *Liber Amicorum Joseph Strauss* 2009.

### 1.2.7 International IPR Regime, Development Agendas

The "international" IPR system, originally created by the Paris Convention for the Protection of Industrial Property of 1883, attempts to provide a uniform international framework within which domestic IPRs, created via national legislation, can operate. The current structure is largely a result of the more recent, international Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement", or "TRIPS"), in 1994 described in detail below.

Many of the obstacles that will be discussed in this report are the consequence of the wide range of countries that are required to participate in the "international" IPR system by international treaties despite their differing domestic laws. The international system requires countries to implement and enforce internationally agreed rules within their national laws and regulations. Although a level of standard-setting is required, given that the TRIPS Agreement permits a range of options, it does not amount to a complete "harmonization" of national IPR laws worldwide.[37]

Developing countries, as discussed in more detail below, are often saddled with a domestic IPR system that is quite inadequate to deal with the demands of modern international trade. In international fora on trade and IPRs, developing countries have argued for more consideration in this regard. In response, concessions have been offered including in such areas as the implementation of IPR standards, "capacity-building" and "technology transfer" (see para. 1.2.8 on infrastructure). Public health problems in developing countries (e.g., medication affordability and access) have necessitated inclusion of mechanisms such as "flexibilities" (e.g. compulsory licensing regimes) and delayed implementation of certain legal requirements in international treaties.

To these ends, and despite resistance from developed states, "Development Agendas" have been established in the framework of the World Trade Organization (WTO) and the World Intellectual Property Organization (WIPO).[38] For example, some opponents argue that WIPO should not deal with development affairs, while others object to having to provide medicines at a lower cost.[39]

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37 As noted above, "international IPRs", an informal term for IPRs as defined in international treaties, is actually a misnomer. Intellectual property rights are national – a patent, for example, is subject to national laws and can only be enforced within the national boundaries (the principle of territoriality). International treaties nonetheless impact national IPRs, and this is where the "international IPR regime" (or: "international IPR framework", "international IPR system") becomes visible. In this report the "international IPR regime" indicates the TRIPS regime in particular (see background and analysis in Chapter 3).

38 WTO: the Doha Development Agenda was agreed at the Doha Ministerial Conference in 2001, with subsequent refinements made in Geneva on 1 August 2004 (The "July 2004 package") and at the Hong Kong Ministerial Conference in 2005. WIPO: at the 2007 General Assembly, Member States adopted 45 recommendations (of the 111 original proposals) made by the Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA).

39 See for a quick background of the Development Agendas: Siemsen & Ahlert 2009. In detail, on the WIPO Development Agenda: De Beer (ed.) 2009; WTO Development Agenda: Gervais (ed.) 2007.

### 1.2.8 Infrastructure

As one source puts it, to lift developing countries above the poverty level many ingredients are essential – a good education system, consistent and coherent economic policies, access to capital, an efficient, reliable, and non-corrupt government, social peace, political stability, entrepreneurship, and a sound work ethic.[40] Other sources point out similar conditions for economic development, and add ingredients for different development dimensions, e.g. socioeconomic, the MDGs, technological and social innovation, functioning IPR systems.[41]

A general term for these requirements is "infrastructure".[42] Infrastructure encompasses, first of all, physical building-blocks of modern states such as: a functioning transport system including railroads, roads, port facilities; a public health network, including appropriately trained medical staff and clinics located in easy reach of the population; means of communication; a potable water supply; and a reliable supply of power. As the MDG Africa Steering Group concluded in 2008, the lack of transport, power, communication networks, water, sanitation and other infrastructure services poses severe constraints on economic growth, trade and poverty reduction across Africa. The Group reported 35 African countries experiencing a power crisis with frequent supply interruptions, with only one in four Africans having access to electricity and only 10% in rural areas.[43]

In addition, various institutional building-blocks are necessary. Importantly, the government must have legal, financial and administrative systems in place. Merely introducing laws, including incorporating international IPR standards into a country's legislation is insufficient: adequate implementation is needed to make the legislation work. To achieve this, a country must have legal and administrative systems capable of coping with a wide range of international demands. Necessary public sector institutions include a legislative branch of legislators and policy-makers, a viable legal and enforcement system with judges and lawyers capable of dealing with complex litigation and sophisticated police and customs agents able to enforce IPR legislation and legal judgments, and a competent patent office with trained examiners and research capabilities.

The concept of infrastructure in developing countries also includes institutions such as universities, research institutes, government funding agencies, organizations of university technology transfer offices, government departments; and, at the international level, organizations such as the United Nations.[44] While these are all public institutions, private sector infrastructure is necessary in developing countries for a functioning economy. A private sector of manufacturers functioning within viable domestic and international markets requires a strong, supportive public sector.

Part of a country's legal infrastructure, in this case its IPR infrastructure, is "enforcement" of IPRs. In short, this means that a system must be maintained based on national policy goals with rights providing adequate protection within the limitations of the laws. It is not enough to have statute books with IPR laws, like the majority of African states following their acceptance of the TRIPS Agreement (see Chapter 3).

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40 Lee 2006, p. 160.

41 See, among others, Hoekman & Kostecki 2009; Odagiri *et. al* (ed.) 2010; Wong & Dutfield (eds.) 2011.

42 Extensively on infrastructure: Hoekman & Kostecki 2009, pp. 386-387, 396, 464, 551, 565; Banji & Padmashree 2010 throughout their book.

43 MDG Africa Steering Group 2008, p. 16.

44 McGill 2008, p. 22.

IPRs do not function in isolation but rather within a country's "innovation infrastructure." (This emphasizes the fact that IPRs are ultimately designed as instruments ((tools)) for economic growth). Technology transfer "North-South" (see para. 1.2.9), too, is considered as having to have an innovation infrastructure in developing (and developed) countries, demonstrating the flexibility of the concept of infrastructure. "Innovation" is understood here in the broad meaning of progress created by the use and application of knowledge.[45] Innovation is often linked with technology, including research and development (R&D), but has a social aspect too, including new methods of organizing a company's workforce and tasks, or establishing new ways of communicating between people.[46] "Capacity-building", associated with development, infrastructure, and innovation, is used here to mean organizational, institutional and human capacity able to deliver development.[47] The relationship between invention and innovation, two different concepts, is not as linear (or clear) as sometimes perceived (see Chapter 4, para. 4.5).[48]

As will be detailed below in Chapter 4, in the context of IPRs, a lack of the necessary infrastructure, using the term in its multiple dimensions, creates significant obstacles.

### 1.2.9 Impact of IPR Law on MDG Policies

As indicated, the MDGs are intended to function as policy instruments to foster development in developing countries. MDG policy planning and implementation, with its close association with trade issues, will inevitably be impacted by international IPR law:

(1) IPRs are usually an integral component of the domestic trade policies of developed countries and as such may interfere with the efforts to achieve the MDGs. However, successfully integrated policies combining trade and development goals are rare with a "development perspective" usually subordinate to a country's international trade policy. In fact, often separate government agencies are involved in development and trade, respectively, making coordination difficult. Modern IPRs are generally designed for and most effective in economically advanced systems. Advanced technology sectors in developed countries generally favor "strong" IPR protection and enforcement to protect their inventions and encourage ongoing R&D. On the other hand, developing countries with a greater interest in acquiring technology and usually weak or even non-existent R&D, favor weaker IPRs. Attempts to combine IPRs with a development policy, even one based on the MDGs, have created obstacles as will be discussed further below.

(2) Technology transfer such as that between public universities in the "North" and users in the "South" may be impacted by existing IPRs with the knowledge, materials and technology involved usually subject to IPRs. Under national IPR laws, those of the Netherlands being a good example, the rights may be controlled either by public universities or the researchers themselves complicating the process of technology transfer even when

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45 Banji & Padmashree 2010, pp. 7-10. Innovation is a quite recent focus of international research with regard to IPRs in developing countries; see Gollin 2008 and Greenhalgh & Rogers 2010 on innovation, IPRs and economic growth.

46 Extensively on innovation, Gollin 2008; Greenhalgh & Rogers 2010.

47 Using Kenya's Prime Minister Paul Kagame's words during a conference on the subject , 11 February 2011, <http://www.acbf-pact.org/capacity-building-in-africa-transcends-mdgs.aspx> (accessed on 1 July 2011) .

48 The concept of "catch-up" is left aside here for reasons of scope; see Odagiri *et. al* (ed.) 2010, p. 2.

intended for developmental purposes. IPR obstacles related to technology transfer are further discussed in Chapter 4.

(3) IPRs will also impact the ability of governments of developing countries to secure easy and affordable access to medicines. This need is particularly acute in developing countries with a high incidence of diseases such as HIV/AIDS, tuberculosis (TB) and malaria. IPRs on pharmaceuticals and diagnostics can have a negative impact on accessibility in these countries particularly where they are responsible for high prices. In the case of agriculture, the problems can be similar with IPRs limiting access to seeds and thereby, it is argued, contributing to problems with food security.

### 1.2.10 Patents: a Significant Part of the Debate on Agriculture, Pharmaceuticals and Diagnostics

Patents are particularly critical in those industries where innovation is central, such as in agriculture (food security/MDG 6) and pharmaceuticals (health/MDG 1).[49] Important in the former are new drugs (e.g., antiretrovirals, anti-malarials) and in the latter such products as genetically-modified seeds. In both cases, "'high-tech' product design is considered the key to competiveness."[50]

Patents provide a temporary and territorial control over the commercial exploitation of inventions. The term "invention", depending on national legislation, may include not only mechanical devices and pharmaceuticals but also scientific or industrial methods or processes – such as how to combine substances or modify a cell's DNA. Again, depending on the domestic laws of individual countries, and generally under the influence of the "North", IPRs have been expanded to include such subjects as geographical indications, database protection, computer programs, genetically modified living organisms and business methods. This will be explored further in Chapter 3.[51]

### 1.2.11 Development Cooperation: the Netherlands–Sub-Saharan Africa

The term "development cooperation" refers to cooperative international action aimed at achieving progress in development. In regard to international development policy, international sources disagree as to what works best in the differing circumstances found in different developing countries.[52] In order to improve the quality of aid consistent with individual country priorities, the MDG Africa Steering Group recommended in 2008 that development partners "fully align their assistance with country systems through multi-year compacts, increase the predictability of aid, improve the division of labor among donors, and accelerate the shift away from project-based finance towards budget support."[53]

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49 Recent works of scholarship on IPRs and public health including access to medicines are, for example, Pogge, Rimmer & Rubenstein (eds.) 2010 and Muzaka 2011; publications on IPRs and agriculture, including food security, include Lightbourne 2009, Blakeney 2009, Wong & Dutfield (eds.) 2011, Chapter 3.

50 Odagiri et.al. (eds.) 2010, p. 421.

51 The involvement of human rights in IPR debates, particularly issues of access (to medicines, seeds) is not explored in this report. There are multiple, recently published sources on that topic, for example, Kur (ed.) 2011; Matthews 2011; Grosheide (ed.) 2010.

52 See Peet & Hartwick 2009; Summer & Tribe 2008.

53 MDG Africa Steering Group 2008, p. 6.

Given the orientation of the primary audience of this report, the Dutch position on development cooperation will be the focus.[54] The Netherlands has been engaged in development programs aimed at countries in the Sub-Saharan Region for over half a century. In recent years, the MDGs and human rights have formed the basis for its development policy for Africa (see Box I-1). To achieve its goals, the Netherlands has worked with fellow-donor countries, the European Commission (EC) and international organizations towards achieving a better quality of life, economic growth and improved governance in African countries.[55] While the aim is to engage in equal-level cooperation programs with African partner countries rather than merely sending "unsolicited" "foreign" ideas, policies and expertise, due to the differences between developed and developing countries, the relationship is unequal. Other determinants of the policy's success include such factors as the willingness on the part of African governments to bring about change and the need to balance trade interests against development efforts, something that requires compromises by industrialized nations.

**Box I-1:** ***Aspects of the Dutch Focus in Development Cooperation.***

*Over the past decades the Netherlands has initiated multiple development programs in African nations based on their specific country profiles.[56] The policy focus has varied. During the 1990s much attention was given to principles of good governance in African nations, i.e., fight corruption and create transparency and accountability.[57] During the 2000s the policy focus was primarily on MDGs and on the consequences of globalization for developing countries. The focus is now shifting to protecting and managing so-called "global public goods"[58] such as water and biodiversity that are considered preconditions for development. Other areas of interest include food security, and health – in particular sexual and reproductive health (mother and child) and associated risks and diseases.*

*Recently, the world economic situation has required a reduction in aid. More focus may in a sense compensate for structurally lower budgets for international development policy by the Netherlands. Among the fifteen countries in total (down from thirty-three) that will enjoy development aid by the Netherlands from 2011-2012 onwards are nine countries in the Sub-Saharan region: Uganda, Kenya, Sudan, Rwanda, Mali, Benin, Ethiopia, Ghana and Mozambique.[59] To give a sense of the size of the Dutch government budget: OECD-figures of*

54 As there has been a change of government in the Netherlands during the time of writing and a new development policy is in the process of being adopted, this report has used policy information from the previous government as well.

55 Policy Coherence 2006.

56 WRR Report 2010.

57 Idem.

58 Kaul, Grunberg & Stern 1999; Drahos 2002a, pp. 215-219; and in Dutch only: *Internationale publieke goederen: karakteristieken en typologie*, web publication no. 41 under the authority of the Wetenschappelijke Raad voor het Regeringsbeleid (WRR, the Dutch the Scientific Council for Government Policy), undated, available at <www.wrr.nl>.

59 As announced to the Dutch parliament by the Ministry of Foreign Affairs-Development Cooperation in a so-called "Focus Letter", 18 March 2011 <www.rijksoverheid.nl)>. See Annex "Focus Letter Dutch Development Cooperation 18 March 2011".

*the year 2008 show that the Netherlands spent 0.8% - or the equivalent of USD 6.993 million or EUR 4.755 million[60] - of its national income on international development affairs in that year. The Netherlands has meanwhile lowered its budget to 0.7% of GNP, on par with the OECD guideline. Additional budget cuts have been announced for 2012, for which it is hoped that the more focused approach mentioned above should compensate.*[61]

Policy coherence, i.e., integrating development policy into trade policy and creating coherence of policies between institutions, is a goal the Netherlands has set out to achieve, but has struggled with.[62] Policy coherence in the area of development requires a government to make sure that development objectives and results are not undermined by other policies of that government; and *vice-versa*, i.e., that those other policies support the development objectives where feasible.[63] The EC seeks to synchronize development policies of the EU countries (see Box I-2).[64] The European states generally recognize a need to avoid overlap in development policies and programs but, despite this goal, still do experience conflicts of interest (see Box I-3).

**Box I-2: *Relationship the Netherlands - European Commission***

*Development Cooperation in the EU is a "joint parallel competence" of the member states and the EU. The European Commission, on behalf of the EU, manages a budget of about EUR 9 billion annually, part of which comes from the member states. The Netherlands annually diverts 10% of its budget for development cooperation to the EC, which would prefer to take the lead in European aid and development programs but national governments are reluctant to transfer more policy space and budget.*

60 Source ECB: historic exchange rate for 2008 is 1 Euro = 1,4708 US Dollar.

61 "Focus Letter", 18 March 2011 (www.rijksoverheid.nl).

62 In Policy Coherence 2006, p. 16 the Netherlands' government laments the lack of coherence between trade policy and development policy on a global scale. In practice, the government appears to have difficulty delivering on this commitment: see box 1-3 *Politics determine development cooperation policies European countries*.

63 Description adapted from the working definition of the OECD, mentioned in Policy Coherence 2006, p. 7. Further, see on national coherence Hoekman & Kostecki 2009, p. 657 ff.

64 'EU 2009 Report on policy coherence for development', European Commission 17 September 2009, COM(2009) 461 final, SEC(2009) 1137 final. See also the following study on Official Development Assistance (ODA) in Europe: Bjorn Tore Carlsson, Carlos Buhigas Schubert & Sarah Robinson, 'The Aid Effectiveness Agenda: Benefits of a European Approach', European Commission-commissioned study prepared by the UK consultancy firm HTSPE, 14 October 2009.

**Box I-3: *Politics Determine Development Cooperation Policies European Countries***

*The official approach taken by the Netherlands has been to seek cooperation with like-minded governments and to enter into dialogue with resistant European countries and interest groups.[65] Most of the larger European countries prefer to pursue their own aid and development agenda, while East-European states lack a tradition of giving aid to Africa. There is also the question of who takes the lead in development programs, which cannot be seen as separate from political status. The Netherlands has stated that it is in favor of the policy of coordinating and streamlining development efforts of the EU countries and the EC; and specializing where possible.[66] The Dutch government, which is currently in the process of adjusting its course on development cooperation, shows no intention of following the EU Operational framework on aid effectiveness (2009, 2011) but instead is moving past the EU-proposed division of aid work including country-choices for the member countries.[67] (See also previous Box I-1).*

Whereas development efforts are seen as having long-term results and need to be predictable over a period of time,[68] external circumstances change all the time. For example, climate change in Africa and the global financial and economic crises of recent years have forced re-evaluation of Dutch policy goals.[69] Rapidly changing circumstances mean that development cooperation is a particularly complex area of government policy.

Studies on the achievements in development cooperation over the years present a mixed picture.[70] One source has reported that as much as one-third of all money spent on development affairs by the Netherlands has been "wasted".[71] Others have concluded that "the world can do very little for Africa, except supporting those that already fight for a better government and a decent life."[72] But even if successes are not systematic, some initiatives have undoubtedly worked and can be used as models.[73] Moreover, as a result of cooperation

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65 Policy Coherence 2006, p. 27.

66 Specialization of donor countries is recommended by the Dutch scientific council for government policy WRR in its January 2010 report on Dutch development cooperation: WRR Report 2010, p. 284.

67 See European Council of the Europe Union 11 January 2011, 'Operational framework on aid effectiveness' (18239/10); also available by following the link to the revised document (2011) on <http://aidresources.org/revised-eu-operational-framework-on-aid-effectiveness-published/>.

68 MDG Africa Steering Group 2008, p. 24.

69 Public information provided by the Ministry of Foreign Affairs.

70 Calderisi 2007; Easterly 2008; Moyo 2009; WRR Report 2010; Van Kesteren 2010.

71 Van Kesteren 2010.

72 Calderisi 2007, p. 207. Critical views of African development and aid programs are many but certainly not all are pessimistic of Africa's potential. For example Moyo 2009, p. 145 opines that the world should stop interfering with African people's lives and watch people take their situation in their own hands.

73 Such as the gradual establishment of ecological self-sufficient communities in Ethiopia for example, with organic agricultures that now produce everything that is necessary to feed and sustain the people in those communities; see <http://en.menschenfuermenschen.com/Projekte/index.htm4> (accessed on 1 July 2011) . Statement in body text is supported by recommendations of the MDG Africa Steering Group 2008.

with developing countries, evidence of how development works is emerging - for instance how knowledge is generated and grows - and can be used to inform future projects.[74]

To date, the debate in the Netherlands has been on specific instruments and direction, not the overall goal of fostering development, which has had unchanging support. The government currently aims at fostering private sector growth in developing countries and knowledge-generation and dissemination. For the latter purpose it has an interest in encouraging involvement of Dutch-based academia and industries.[75] In addition, the government is aiming at setting up networks with African knowledge institutions and private sectors. As part of its support of the MDGs, it hopes to achieve innovation in African business sectors and research institutes. Facilitating innovation by contributing ("transferring") technology from the Netherlands will be affected by IPRs as the technology in question is generally controlled by the holders of private rights.

**Box I-4:** ***The Use of "North-South" Terminology***

*Consistent with today's international development "language," this report uses the term "North-South" relationships when considering relations and partnerships between the industrialized world, in this case the Netherlands, and the developing world, in particular countries in Sub-Saharan Africa. As often happens, particularly with policy terms, both the meaning and the language itself change to suit either new directions or prejudices (or both). Even though the image attached to "North-South" relations is imperfect, the authors have chosen this terminology as the most useful for the subject matter of this report. Even the MDGs, established over 10 years ago, include language whose connotation has altered over time. The relatively new focus on knowledge and innovation in development affairs brings "new" terminology with it such as "building knowledge-infrastructure" and "strengthening knowledge-capacity".*

## 1.3 Following Chapters

The following Chapters identify and describe the obstacles impacting the process of achieving development goals. As indicated above, this report will be divided into four sections, each corresponding to a specific theme. Chapter 2 will describe those obstacles that are part of the legal system comprising IPRs. Because patents are most relevant to this project, the primary focus of this report will be on the patent system. Next, in Chapter 3, the focus will be on the system of international IPRs with particular attention on how the requirements of the TRIPS Agreement impacts achieving the MDG goals. In Chapter 4, the intellectual property "infrastructure" of developing countries will be discussed, in particular the question of how infrastructure has impacted the ability of both developed and developing nations to fully implement the changes required to achieve the MDGs. Although "enforcement" of IPRs is a subject in itself, it is also a component of the international IPR system and infrastructure. Therefore, obstacles relating to enforcement will be integrated in the other Chapters, in particular Chapter 4. In Chapter 5, the obstacles will be discussed arising from the "power

74 View based on Banji & Padmashree 2010.

75 See for links with Dutch sectors of economic importance, for example "life sciences": Annex "Focus Letter Dutch Development Cooperation 18 March 2011" (in Dutch only).

differential" between developed and developing countries – the term "power" being broadly applied to political and economic factors that determine the difference in power. Chapter 6 will contain conclusions and some recommendations.

# CHAPTER 2 OBSTACLES RELATED TO THE NATURE AND GOAL OF INTELLECTUAL PROPERTY RIGHTS

## 2.1 Introduction

IPRs, such as patents and copyrights, are time-limited legal monopolies that have developed over a number of centuries.[76] The "underlying values of a society" are reflected in the decisions regarding "what" is to be protected and "how" such protection should be implemented.[77] Common to both "western intellectual property laws" and those found in "indigenous societies" is that both aim to "enhance public welfare by protecting the fruits of creative effort."[78]

In the Anglo-American view, people "make choices which will maximize their individual welfare."[79] In exchange for public disclosure of the invention, inventors are permitted, for a limited time, the sole right of exploitation before it enters the public domain and all are free to manufacture, use, sell or offer to sell, improve or develop it.[80] However, this view is not necessarily shared by other states whose own unique cultural perspective informs their "understanding of what constitutes property or what may rightfully be the subject of private ownership."[81]

Despite similarity of goals, IPRs are national. Each state, depending on its underlying values has its own IPR system - an invention patented in the United States, for example, is not protected in another country (unless, of course, the inventor is granted a patent by that country).

## 2.2 The Traditional "Western" Patent "Story" - the Goal of IPRs

The traditional patent (IPR) "story," as expressed in Western, developed nations, is that, without a financial incentive, most individuals will have neither the motivation to invent nor the interest in developing an invention for general use. Society, through patent law, offers the inventor a "deal". For a limited time, the inventor may benefit from the invention, for example, by using, manufacturing, selling or improving it. In exchange, its details will be made available to the world in sufficient form to allow one "skilled in the art" to practice the invention. After this limited period, in modern patent law 20 years from the filing date, the invention is available to all who wish to exploit it. The traditional patent story therefore ends with an inventor who, thanks to IPRs, has recouped the cost of his research and development and been rewarded with a fair profit while providing society with the benefits of his invention and permitting others to exploit it further.[82] (See Box I-7). The question, of course, is whether this "story" represents reality.[83] Regarding whether IPRs fulfill their intended goal of

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76 See, generally, for example <http://www.wto.org/english/tratop_e/trips_e/intel1_e.htm> (accessed on 1 July 2011) .

77 Gana 1995, p. 112.

78 Gana 1995, p. 136.

79 Gana 1995, p. 116.

80 This information can be found in textbooks on IPRs, see, for example Cornish & Llewelyn 2007; for the US context, see Merges & Fitzgerald 2010.

81 Gana 1995, pp. 115-116.

82 See for general background of IPRs, for example Ricketson & Creswell 2006; Maskus 2000.

83 Critical of this "story": Chamas, Prickril & Sarnoff 2011, p. 64.

rewarding the inventor and disseminating knowledge, "(t)he evidence so far is mixed: under certain circumstances, intellectual property rights indeed further the dissemination of important innovations; under different circumstances, they do the opposite."[84] (See Box I-5).[85] The relationship between IPRs and development is often described as "complex, multifaceted and dynamic."[86] In the fields of mathematics and physics, as an example, progress has occurred without resorting to IPRs.[87] (However, note that, in some countries, the products derived from abstract mathematical and physics formulae may be patentable.) (See Box I-6).

**Box I-5:** ***The IPR Story***

*Different states have different IPR regimes which are usually the product of a combination of legislation, administrative regulations and court decisions. Patent laws are intended to achieve various objectives – they define what is patentable, the breadth (or scope) of a patent, the rights of patent owners, the duration of these rights and how patents are granted.[88] Most countries agree that to be patentable an invention must be new and have an "inventive step" (European patent law versus the "non-obviousness" standard in the United States)[89] in relation to existing scientific and technical knowledge.[90]*

*These rules or regulations must be constantly updated to keep up with the advances of science. In addition, most countries include protection against IPRs being used to stifle competition. Poorly drafted patent legislation, or inadequately examined and approved patents, can produce significant problems. Several factors determine the effect the "technical" aspects of patents may have on innovation and development. Patents are primarily legal documents whose essential function is to define the disclosed "invention" in sufficient detail to let the world know exactly what the limits are of the area of technology claimed by the inventor i.e., what is forbidden territory and what is available for others to exploit. The rules pertaining to how these documents are written can impact their effect. For example, patents define the boundaries (or limits) of an invention. MPEP 2171 notes that 35 U.S.C. 112 requires that the patent claims must point out and "distinctly define the metes and bounds of the subject matter" that will be protected by the patent.[91] The purpose of this to ensure that "the public is informed of the boundaries of what constitutes infringement of the patent."[92] Poorly written patents*

84 Henry & Stiglitz 2010, p. 238.

85 Henry & Stiglitz 2010, p. 248.

86 Li & Correa (eds). 2009, p. 3.

87 Henry & Stiglitz 2010, p. 240.

88 See, for example, Article 83 EPC. Art. 112 Utility Patent Act, Art. 83 EPC and Art. 29 TRIPS all deal with the same issue: disclosure in return for temporary control (exclusivity).

89 A footnote to TRIPS Article 27.1 notes that the terms "inventive step" (EPC) is synonymous with "non-obvious" (US) and "capable of industrial application" (EPC) with "useful" (US).

90 See, Chapter 4. See, generally, for the European approach, <http://www.epo.org/law-practice/legal-texts/epc.html> (accessed on 1 July 2011).

91 Manual of Patent Examining Procedure "MPEP" is the core publication of the United States Patent and Trademark Office (USPTO) and is continuously updated as laws and regulations change. The MPEP represents the USPTO position on virtually every point of law and procedure.

92 *MPEP* 2173, see previous footnote.

*with poorly defined boundaries inhibit innovation as inventors in the field are reluctant to infringe an existing patent and have their work subjected to litigation.[93] (As an analogy one may consider "real" property. If the boundaries of a piece of land are poorly defined and determined, others are reluctant to build on adjoining property being concerned about the possibility of trespass litigation.)*

*The "breadth" of a patent refers to the extent to which the patent includes ("encloses" to use a real property analogy) a field of technology. Considered another way, the breadth of a patent can be characterized by "the minimum degree of differentiation that a new product must entail with respect to the product covered by the patent in order to avoid infringing the patent."[94] A patent of excessive breadth (i.e., overlying broad claims) will, instead of teaching new knowledge on which others can build, will merely act as a roadblock by giving the inventor more than he actually invented.[95] When patents are overly strong, downstream research is hindered making future innovation more costly and strengthening entry barriers to competitors.[96]*

**Box I-6: *Pharmaceutical Patents***

*One of the industries that relies most heavily on patents is the pharmaceutical industry. The pharmaceutical industry has long argued that without the protection afforded by patents they lack the (financial) ability to fund essential research and development.*

*The cost of developing a new drug is massive. The estimated cost of developing a single new drug varies from $800 million to nearly $2 billion.[97] Recently, Pfizer announced that it is investing $800 million just for a set of Phase III trials for a single drug.[98] Considered another way, the cost of R&D has steadily risen into the billions of Euros: € 2.4 billion on average for each of the 18 truly new pharmaceuticals in 2008, as compared to € 1.3 in the year 2000. Note that having spent all this money, a company still may find that problems at a later stage of development mean that the drug is, for example, unsafe for humans, and therefore the entire project is abandoned - this before the company has recouped even $ 1 from its outlay.*

*While the cost of developing a new drug is massive, the potential rewards of a "blockbuster" drug are huge. Merck & Co. reports that it will focus on investing in further drug development after spending $8.1 billion on R&D last year. Merck's No. 1 seller, the allergy and asthma medicine Singulair, will start facing competition from low-priced generics in the U.S. in August 2012. Last year, the drug was responsible for $5 billion of Merck's $46 billion in total worldwide sales. Pfizer spent $9.4 billion on R&D last year. Pfizer's top-selling product, the*

93 This is a well known concept in patent law practice, often discussed in texts on "claim drafting"; see, for example, Merges & Fitzgerald 2010.

94 Henry & Stiglitz 2010, p. 241.

95 Henry & Stiglitz 2010, p. 241.

96 The drafting of patents and their subsequent value as legal documents is a complex subject implicating national laws and regulations, the effectiveness of the granting patent office and decisions by courts. A detailed discussion of this topic is beyond the scope of this report. Reference to standard texts on the issues are recommended.

97 'Focus on Intellectual Property Rights', US State Department Publication, available at: <http://www.america.gov/media/pdf/books/iprbook.pdf#popup> (accessed on 1 July 2011).

98 *Idem.*

*cholesterol fighter Lipitor, will lose its patent protection in the U.S. in November. The drug had $10.7 billion in world-wide sales last year, nearly 16% of Pfizer's revenue.*[99]

*Given these pressures, companies have to choose where they spend their R&D money wisely and look at alternative business approaches. Generally what happens is that they continue to exploit their patented drugs, but stop heavy investments in the development of new medicines. To secure their future prospects they take over smaller companies with usually one successfully developed drug. They can exploit this drug and at the same time "kill off" any ongoing development of new drugs in this smaller company to avoid the threat of real competition through new investments.*[100] *Thus, despite their claims of dependency on and the importance of the patent system, pharmaceutical companies are experiencing a lack of in-house innovation. As yet, there does not appear to be a solution to this problem.*[101] *A possible alternative would see pharmaceutical companies seeking alternative financing for R&D through public-private partnerships via partners in government and university circles. Such an approach would be quite acceptable in the Netherlands where the government supports public-private partnerships as an instrument for fostering development in the "South" and jointly working towards achieving MDGs.*[102]

**Box I-7: *The Nature of IPR***

*IPRs, the products of legislation and judicial decisions, enable a country to manage its intellectual property.These laws and regulations determine what constitutes patentable subject matter, the procedures by which patents are granted, the scope of protection provided by a specific patent and the rights and obligations of the patent owner. For example, to be patentable an invention must be new (novel), must contain an "inventive step" ("non-obviousness" in the US), and have a practical utility. The inventor must completely disclose the invention. The laws and regulations that make up IPRs are not static, changing as technology changes and inventions considered science fiction a decade ago are now commercially viable (see Chapter 1, para. 1.2.6). A further consideration involves the "deceptively simple terminology" of TRIPS that requires developing countries not only to adopt "new standards" but also have a "judicial or administrative history to provide content to these terms.*[103] *Unfortunately, developing countries have "little judicial involvement" in the maintenance of the laws that regulate their patent systems, contrary to, for example, developed countries like the United States and Europe that rely on a "complex application of rules" by courts "which has been carefully developed and applied" over a period of many years.*[104]

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99 As reported in *The Wall Street Journal*, 3 February 2011.

100 Uitdehaag 2010, p. 7.

101 Engelenburg 2010, p. 11 and Uitdehaag 2010, p. 7.

102 Ministry of Foreign Affairs, <http://www.minbuza.nl/nl/Onderwerpen/Bedrijfsleven/Partnerschappen>, in Dutch, accessed on 6 November 2010.

103 Gana 1996, pp. 748-749.

104 *Idem.*

**Box I-8:** ***Patents as Commodities***

*As illustrated in the following news report, patents are an important part of modern sophisticated economies:*
*Canada's Nortel Networks Corp., which filed for bankruptcy in 2009, "expects to select an initial bidder for a massive portfolio of patents within three weeks, drawing from a pool of at least five potential buyers including Apple Inc. and Google Inc. … This portfolio contains a set of patents related to the emerging technology used in long-term evolution, or LTE, wireless phone networks. … The deal, expected at around $1 billion, would be a preliminary 'stalking horse' bid filed with the Delaware bankruptcy court … Patent litigation has gotten more contentious in recent years, particularly in the market for wireless devices. For instance, Apple is engaged in a patent fight against Nokia, while Microsoft Corp. and Motorola have exchanged patent suits related to phones."*[105]

Patents are intended to encourage an inventor to disclose their invention to the public. By this means it is hoped that the incentive to invent will be encouraged to the benefit of society in general. However, an IPR regime may, depending on how it is structured, have the opposite effect. Poorly defined and delineated patents may act as inhibitors of invention as potential developers are turned off by fears of infringement litigation. This lesson is important to countries, particularly developing states who are obligated by international trade treaties to modify or even introduce their own IPR systems.

In summary, while IPRs are an important and valuable component of innovation, care must be taken to ensure that they do not impose too great a cost on research by "restricting access to some elements in the streams of creative thought."[106]

## 2.3 IPR Systems

Generally, the more advanced a country is in terms of industry, research, technology and related areas, the greater the perceived need for patent protection. Factors that determine the appropriate level of IPR legislation (i.e., patent protection) required in a particular country are (i) its level of research and development (R&D), (ii) its market environment, and (iii) international integration.[107] Given their overall lack of industrial sophistication, an approach to developing countries would be first "to foster a significant research base in (developing and least-developed) countries (which would) thereby create incentives for protecting patent rights," as discussed below.[108]

A further consideration is the type of economy in which the modern patent system operates. In a market that permits free interplay of competing forces, one function of the patent system is to be a mechanism that contributes to a reduction of transaction costs and helps a society "gauge inventions in a relatively efficient manner."[109] In a free enterprise economy, the likely value of an invention can be determined once its details are disclosed via

105 As reported in *The Wall Street Journal*, 3 February 2011.

106 Henry & Stiglitz, 2010, p. 240.

107 Claessens 2009, pp. 519-520, 539.

108 Ginarte & Park 1997, conclusion referenced by Claessens 2009, p. 519, footnote 264.

109 de Carvalho 2005, p. 53.

publication of a patent and it enters the stream of commerce. Competitors then decide whether to invent around, create a competing device or drug or other product, seek a license from the rights holder, or infringe and thereby challenge the patent within the legal system.

In the typically centrally-planned economy found in most developing countries, patents are unable to fulfill this crucial marketplace function of evaluating inventions.[110] In a centrally-planned economy, potential inventors often rely primarily on public subsidies and, even if there is a national patenting system, there is no real free competition as there is "neither antitrust legislation in place nor the experience (to) enforce it."[111] Antitrust law provides the means of ensuring that the patent system does not lead to anticompetitive behavior by patent owners.

### 2.4 Use of IPRs: Different Goals

A further problem in achieving the core objective of patent law – "stimulating innovation" – is that this is not always the only motive of the rights owners. While the generally stated rationale for patents is providing an incentive to innovate in return for the duty to disseminate an invention to the public, their use has expanded far beyond this. Patent rights owners may "have different goals or interpret similar goals in different ways."[112]

Patents have themselves become commodities. For example, companies have used patents to enhance their assets or "set IP traps for potential competitors."[113] The incentive to pre-empt rivals might encourage a firm to patent its inventions but not because it intends to enlarge the field but rather to "get just far enough ahead of rivals so that (they) are discouraged from competing."[114] This approach actually impedes development in the field. Another use for patents has been as a means of blocking competitors. Owning a patent provides certain rights to the holder such as preventing others from manufacturing, using or importing a product. The enforcement of these rights, however, should not permit engaging in anti-competitive behavior. To use a metaphor, owning a baseball bat may permit one to play baseball but not use it as a weapon.[115]

### 2.5 Use of IPRs: Costs of Patenting

A further consideration is the direct and indirect costs of patenting. By increasing the cost of medicines and seeds to levels where they cannot be afforded by developing countries, patents threaten public health and food security. Whether this can be blamed on IPRs themselves, insufficient finances of individual households and governments, or a lack of absorption and skills to utilize the technology is debatable, the answer perhaps depending on one's political view.

Newly developed medications and seeds, particularly once protected by patents, are expensive and as a consequence are unlikely to be afforded by those developing countries which urgently require their use. Pharmaceuticals are a good example of an industry where

110 *Idem.*

111 *Idem.*

112 Van Overwalle (ed.) 2009, p. 397.

113 McGill 2008, p. 22.

114 Henry & Stiglitz 2010, p. 239.

115 To paraphrase Henry & Stiglitz 2010, p. 241.

patents increase the cost of protected products.[116] The traditional business model of the pharmaceutical industry requires extensive spending on R&D, which the industry claims must be recouped from its sale of new drugs. Patenting provides the mechanism whereby this can be achieved with the result that the costs of R&D can be passed onto the consumer. Of course, states that have sufficient funds will never lack adequate antiretroviral treatment (ARVs) regardless of where the price is set. Unfortunately, developing countries are not in such a favorable position, given their significantly more limited funds. In this case, having less financial resources suggests a narrower range of options for accessing public goods that are relevant to achieving the goals of the medical MDGs.

Pharmaceutical manufacturers insist that without having the avenue of patent exploitation to recoup their costs, they would be unlikely to pursue the expensive R&D including, for example, clinical trials, necessary to develop these inventions. Other sources of R&D funding could be found most likely deriving directly or indirectly from public funds. Such a use of public funds in developed countries, particularly if primarily for the purpose of reducing cost in developing countries is likely to be met with resistance. Essentially, it would mean that the consumers in developing countries would be permitted by the consumers of developed countries to "free ride" on the inventions they have subsidized. This means that the commercial exploitation of patented medicines will be an important component of R&D funding.

Even in developed states, traditional views of the patent system and the way it is used are being called into question. For example, the International Expert Group on Biotechnology, Innovation and Intellectual Property ("The Group") organized by the administration at the Centre for Intellectual Property Policy at McGill University's Faculty of Law, in conjunction with a range of experts in the field, following a seven-year study on the effects of IPRs on biotechnology, issued a report entitled "Toward a new year of Intellectual Property: from confrontation to negotiation."[117] Their "core finding" was that changes in the IPR system are necessary.[118] According to the Group, the previous, ("old") approach to IPRs, dependent as it is on "more" IPR, has been "counterproductive to industry" with "declining levels of innovation despite increasing stakes in intellectual property."[119] The Group suggests that the way in which IPRs are used has led to dissatisfaction with the IPR system.[120] Further, again in regard to innovation, the Group concluded that the current IPR system has been "counterproductive to the world's poor who await advances in health and agriculture long available to the global elite."[121]

## 2.6 Conclusion

IPRs, particularly patents, are a legal mechanism designed to provide inventors with a time-limited monopoly for their invention with the goal of both encouraging and rewarding inventive effort. IPRs developed over a period of centuries in progressively industrialized societies.

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116 On price controls, see for example Chamas, Prickril & Sarnoff 2011, pp. 76-80.

117 McGill 2008.

118 McGill 2008, p. 7.

119 McGill 2008, p. 7.

120 McGill 2008, p. 12.

121 McGill 2008, p. 7.

While it is generally considered that it is in developed societies that IPRs are most effective and serve their primary role of stimulating innovation, more recently, their effectiveness in this regard in less industrialized, still-developing societies (and even, according to some, in developed states) has come into question.

As discussed above, the appropriate level of national IPRs in a state is related to i) its level of research and development (R&D), (ii) its market environment, and (iii) international integration.[122] Imposing IPRs on developing states that lack the appropriate level of these factors would only serve to inhibit development and innovation, a likely significant obstacle to achieving MDGs.

Experts in biotechnology, innovation and IPR judge the current international IPR system "counterproductive". They note declining levels of innovation in industries in the developed world despite an emphasis on "stronger" IPRs; they also conclude that it is the way in which IPRs are used by the right holders that creates dissatisfaction with the IPR system (more than the fact that the IPR rules are there).[123]

As the next Chapter will demonstrate, imposing IPRs on developing states in an attempt to standardize the international IPR regime has been a source of additional obstacles.

[122] Claessens 2009, pp. 519-520, 539.

[123] McGill 2008, p. 7.

# CHAPTER 3 THE INTERNATIONAL IPR REGIME – TRIPS

## 3.1 Introduction

Intellectual property rights (IPRs) are "culturally construed and negotiated between the state and private interests" within each individual state.[124] Each country creates and manages its own IPR regime which is only enforceable within its borders. This Chapter reviews and analyses attempts by the international community to harmonize disparate national IPR regimes and create an international system that permits monitoring and policing members. As discussed below, this attempt at creating a level playing field for intellectual property laws and regulations between separate states and at the same time creating mechanisms for enforcement of IPR rights, while solving some problems, has created unexpected obstacles.

This Chapter concentrates specifically on those obstacles arising from the "Agreement on Trade-Related Aspects of Intellectual Property Rights" (TRIPS), the dominant international agreement in this area. TRIPS was negotiated during the Uruguay Round of GATT when developed states felt obliged to institute internationally recognized IPRs supported by powerful enforcement tools that were lacking in earlier agreements such as the Paris or Berne Conventions.

It was hoped that by creating a functional international IPR system, with powerful enforcement capabilities, intellectual property flowing from the developed to the developing states would be protected. The "strong levels of intellectual property protection" found in TRIPS would "enhance domestic and global welfare."[125] Unfortunately, the means by which developed states created and imposed the international system, particularly when considered in the context of the history of colonialism, resulted in developing states failing to give their whole-hearted support to the system. In fact, the history of developing states and international IPRs has been a long one of frustration and unrealized expectations.[126]

These issues must be considered within the context of a government's dual, and often contradictory, "domestic" and "international" responsibilities. The problem for individual states is how to fulfill the demands of the WTO "multilateral trade system" while at the same time serving domestic interests.[127]

## 3.2 TRIPS Background

The history of IPRs in developing countries dates from the period of "empire-building and colonization" during which time the "movement of intellectual property standards (was) from developed to developing countries."[128] This period was characterized by developed states imposing their national IPR regimes on their African colonies through "various forms of informal" administration.[129] This process occurred, not for the direct benefit of the developing nations but rather "to facilitate commercial relations among colonial powers."[130]

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124 Okediji 2003b, p. 317. See also Gervais 2007a, pp. 13 and 28.

125 Okediji 2003a, p. 836.

126 See, generally, Correa & Yusuf (ed.) 2008, Okediji 2003a, Gana 1996.

127 Okediji 2003a, p. 831, footnote 26.

128 Drahos 2002b, p. 7.

129 Okediji 2003b, p 323.

130 Okediji 2003b, p. 324.

With regard to their colonies, the goal of intellectual property law was seen as achieving the purpose of the "colonial strategies of assimilation, incorporation and control."[131] The impact of the Paris Convention of 1883 (patents) and the Berne Convention of 1886 (copyright), both the foundations of the modern international IPR system, was felt by "the colonies and foreign territories controlled by a few European sovereigns."[132]

In the post-World War II period, both developed and developing countries were dissatisfied with the international IPR system. Attempts at modifying the Paris Convention were successfully blocked by developing countries producing a "North-South stalemate."[133] Developing states not only managed to prevent strengthening of the Paris Convention but also sought its mitigation by seeking "lower and more flexible standards of intellectual property protection, both domestically and internationally."[134] For example, India, a newly independent nation, undertook to "redesign" its patent laws to "suit her own national circumstances."[135] The resulting legislation, which was to lay the foundation for modern India's powerful generic pharmaceutical industry, included limiting patents to the methods of manufacture only and not the pharmaceuticals themselves and reducing the term of protection for drugs to seven rather than 14 years.[136] Similarly, Brazil, Argentina, and Mexico revised their patent systems passing laws that "saw patent rights in the pharmaceutical area weakened."[137]

Developed countries, notably the United States, faced a different kind of challenge in the form of both the "vulnerability of information products" to piracy and a "declining capacity to rival manufacturing centers in newly developing economies of Asia."[138] As "increasing globalization and international trade (…) brought new external pressures on developing countries to reform their intellectual property systems," developed countries sought to create and impose an entirely new international IPR regime.[139] The problem was how the international system should be expanded, or adapted, to allow countries of "disparate levels of economic and technological capacity" to join.[140]

Developed countries, which "already shared substantially similar levels of intellectual property protection,"[141] became concerned about the growing power of developing states in the various international organizations such as WIPO, UNCTAD and UNESCO in which developing states were in the majority and therefore were able to block attempts at strengthening international IPRs.[142] (See Box I-9).

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131 Okediji 2003b, p. 325.

132 Okediji 2003b, p. 315, footnote 1.

133 Okediji 2003b, p. 327, footnote 45 referencing Paul Simon, 'Cooperation Between the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO)', *St. John's J. Legal Comment*, pp. 429 and 433.

134 Correa & Yusuf (ed.) 2008, p. 7.

135 Drahos 2002b, p. 8.

136 *Idem.*

137 Drahos 2002b, p. 9.

138 Okediji 2003a, p.128.

139 Li & Correa (eds.) 2009, pp. 4-5.

140 Okediji 2003b, p. 325.

141 Okediji 2003a, p. 827.

142 Drahos 2002b, p. 10.

The original motivation to consider a "trade-based strategy for securing greater protection of intellectual property rights" came from private industry.[143] In fact, industry groups were created that extended beyond national boundaries and "leaned heavily on their respective states" that "made the necessary compromises to stabilize their coalition."[144] In a classic "forum-shifting" move, the United States turned to the forum where it was "the single most influential player," the General Agreement on Tariffs and Trade (GATT).[145] Developing countries, which were more comfortable with WIPO, resisted this approach arguing that "GATT was primarily concerned with trade in goods and not personal rights of property in intangibles."[146] Nevertheless, developed countries proceeded via the Uruguay Round of trade negotiations under GATT. When developing countries continued to express their reluctance to participate in the negotiations, they found themselves pressured "through threats or actual exercise of Section 301 power."[147] The US, the initial driving force for inclusion of intellectual property issues in the Uruguay Round, was eventually supported by "a coalition of forty countries, and (its approach was) adopted by the Ministerial Conference in Punta del Este."[148] (See Box I-10).

**Box I-9: *WIPO***

*The World Intellectual Property Organization (WIPO) was established in 1967 - becoming a specialized agency of the United Nations in 1974 - with the goal of promoting world-wide intellectual property protection. However, in the view of the large multinational pharmaceutical companies, by not creating higher patent standards, WIPO had proved inadequate.[149] Firstly, developing states, which had previously had a limited role in WIPO IPR standard creation and setting, were now taking a more active role in opposing and rebutting developed country proposals whereas previously their interest was more in receiving technical support to implement IP treaties. Secondly, WIPO treaties offered only minimum standards of protection and insufficient enforcement power.[150]*

**Box I-10: *The World Trade Organization***

*Following World War II, as part of a plan to effect a world-wide economic recovery, the Bretton Woods Conference was convened. Out of this emerged the General Agreement on Tariffs and Trade (GATT) and, in 1994, the World Trade Organization (WTO). The WTO is tasked with managing the rules of international trade as negotiated by its Members. The Final Act of the 1986-1994 Uruguay Round of Trade Negotiations, actually the first of a series of agreements, deals with various WTO activities that include the implementation of IPRs. Through the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), the WTO*

143 Okediji 2003a, p. 844.
144 Okediji 2003a, p. 848.
145 Drahos 2002b, p. 10.
146 Drahos 2002b, p. 13.
147 Okediji 2003a, p. 844.
148 *Idem.*
149 Drahos 2002b, p. 9.
150 Li & Correa (eds.) 2009, p. 6.

*manages trade disputes between states. This "celebrated" dispute resolution system has been an "important mechanism in transforming national intellectual property legislation worldwide."[151] The Dispute Settlement process has resulted in "several important disputes" being settled.[152] Another function of the WTO is providing technical assistance to developing countries. The GATT principles implemented via TRIPS include: (i) most-favored-nation treatment (Article 1) whereby a nation is required to provide to the nationals of all Members the same favors, privileges or immunities granted to the nationals of any other country, (ii) national treatment of goods (Article III) (Members shall accord to nationals of other Members the same rights and privileges with regard to IP protection that it provides to its own nationals), and (iii) elimination of quantitative restrictions (Article XI). The TRIPS Agreement incorporates significant aspects of the Paris and Berne Conventions which, since the 1880s have formed the core of the modern international intellectual property protection system.*

The World Trade Organization (WTO) is an international organization dealing with the rules of trade between nations. An important role of the WTO is to provide global markets with the confidence that trade with developing states will not be distorted through massive abuse of IPRs and corresponding infringing goods. It seems reasonable that with a properly functioning IPR system and an appropriate supporting infrastructure, multinationals will be more willing to engage in trade with, and transfer technology to, developing states. Such a situation, developed nations claimed, will have a "positive role in encouraging the establishment of partnerships between firms of developed countries and those of developing countries."[153]

The "attitude" of developing states, on the other hand, "was often belligerent" demanding "compensation, in the form of concessions, from developed countries for the wrongs of colonialism."[154] This attitude, a "deep distrust of policies and programs initiated at the behest of Western nations," complicates resolving the key issue at the "heart of the conflict between developing and developed countries … a conflict of ideologies over what constitutes proper subjects of property rights."[155]

Developed states had high hopes for the GATT negotiation process, which was structured differently than the WIPO system. In WIPO negotiations, the focus is on "the direct arguments for and against higher standards of protection."[156] The GATT negotiations, on the other hand, were designed to "force developing countries to offer concessions on IPRs in exchange for what they might gain in other fields (e.g., agriculture, textiles, and tropical products)."[157] The GATT mechanism also "provided for effective enforcement of agreements and for dispute settlement mechanisms, both of which were lacking in the WIPO-

151 Okediji 2003a, p. 820.

152 *Idem.*

153 de Carvalho 2005, p. 129.

154 Gana 1996, p. 737.

155 Gana 1996, p. 745. Different TRIPS negotiation narratives are contextualized by Gervais 2007, pp. 5-17 with reference to Yu 2005.

156 Correa & Yusuf (ed.) 2008, p. 9.

157 *Idem.*

administered conventions."[158] As can be appreciated, this approach was not conducive to positively influencing weaker trading partners.

Although initially very resistant, developing countries were persuaded to accept higher IPR standards utilizing the GATT-based approach.[159] Their participation was achieved by: (a) the US making effective IPR protection a condition for access to the US market for developing countries with promises of lowering tariffs and quotas and reducing agricultural subsidies (the "carrot"); (b) the US and later the EEC (now the EU) threatening trade retaliation if IPR protection in a developing country was not considered sufficient (the "stick"); (c) effective IPR legislation was equated with a good conduct certificate as developing countries adopted free market policies; and (d) developing countries hoped that acceptance of a multilateral framework was preferable to bilateral concessions and might in any case lead to trade-offs in other areas.[160]

In addition, developing states hoped that TRIPS participation would relieve them from threats such as the unilateral trade sanctions threatened by the US Trade Representative "Special 301" Report and the high standards of IPR protection mandated by their various regional and bilateral trade agreements involving the US.[161]

The GATT negotiations were not completely one-sided even though critics complain that the "(a)greement in many respects reflected prevailing U.S. law and policy."[162] During the negotiations, a group of developing nations (the so-called Group of 14[163]) did manage to include a number of objectives and principles considered by them to be especially important. Their proposals for inclusion in the agreement include areas ranging from counterfeit goods to "the standards and principles concerning the availability, scope and use of intellectual property rights."[164] The objectives and principles were incorporated in some form but not all the concerns or expectations of the Group of 14 were addressed to their complete satisfaction.

### 3.3 TRIPS and "TRIPS-plus": Implications

TRIPS identifies "both what must be protected and how," including administrative processes and minimum protection standards and remedy obligations.[165] Prior to the passage of TRIPS,

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158 *Idem.*

159 Note that the United States also had to modify its law as part of the domestic implementation of the TRIPS Agreement via the "GATT legislation"; Uruguay Round Agreements Act, 108 Stat. 4809, 4973-4990 (1994). Examples of changes introduced into US patent law included changing the expiration date of US patents to 20 years from the date of application filing, expanded the definition of infringement to include the acts of unauthorized offering for sale and importing and added a new procedure for filing "provisional applications" (Merges 2002, p. 58).

160 Correa & Yusuf (ed.) 2008, p. 9.

161 "Special 301" provisions of the US Trade Act of 1974 require the US Trade Representative to identify those countries that do not sufficiently enforce IPRs or impede domestic market access by US companies. Once thus identified, the US can withdraw trade benefits or impose duties on imports from these countries. See, section 305 of the Trade and Tariff Act of 1984 and 19 USC section 2242 referenced by Drahos 2002b, p. 13.

162 Okediji 2003a, p. 825.

163 The "group of 14" consisted of Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe.

164 Correa & Yusuf (ed.) 2008, p. 9.

165 Gana 1995, p. 121.

and the requirement to comply with it, developing and least-developed countries were in the main left with the legal systems of their colonial period. In regard to intellectual property protection, this included excluding patents for pharmaceuticals from patentable subject matter (e.g., India, Thailand, and Brazil), compulsory license provisions (e.g., Argentina, Korea, and Thailand) and weak enforcement mechanisms.[166]

For many industrialized countries, TRIPS, as part of their international trade strategy, represented only the next step towards ever stronger IPRs, whereas developing countries are still struggling with implementing TRIPS-compliant systems. From the point of view of developed states, the TRIPS agreement that emerged from the GATT negotiations, did achieve its goals via the WTO dispute settlement system, trade remedies and sanctions to enforce obligations.

While the TRIPS Agreement did allow a delayed implementation schedule for developing and least-developed countries and the WTO Dispute Settlement Understanding had "different expectations for least-developed countries," developing states remained dissatisfied.[167] The passage of TRIPS meant they had to reform their national IPR systems. From their point of view, TRIPS promotes the interests of the developed "North" at the expense of the less developed "South".[168] They perceive it as favoring the rights of the "North", with its emphasis on private property ownership, over their own public interest. Following TRIPS ratification, developing countries continued to seek allowances with regard to their economies and development needs, consistent with their proposals in 1970s through the 1990s. However, as before, they did not have the power to forge major changes in the international IPR system (see Box I-11).

Acceptance of TRIPS usually required the IPR laws of developed and developing countries to be changed. For example, in pharmaceutical IPR protection, before TRIPS, patent duration of both developed and developing countries varied with terms ranging from 15 to 17 years. TRIPS requires a uniform grant of twenty-years of protection.[169] Also, before TRIPS came into force, some countries provided only "process patents," not "product patents". Process patents provide for protection for the specific process or method of manufacturing a product. As such, if a manufacturer is able to create the same product using a different process or method, the patent is not infringed. On the other hand, product patents provide protection of the product regardless of which process or method was followed in its creation.[170] An IPR regime providing only process patents would allow the manufacture of pharmaceuticals patented as "products" in other countries so long as an alternative method or process was used. In a system that permitted product patents, a drug would be protected regardless of the method used in its manufacture. This latter system would be considered a "stronger" form of IPR. In many developed countries, the United States being an example, products are protected by *both* process and product patents.

Much of the ongoing controversy surrounding TRIPS has to do with diverging political agendas over trade-related interests of developed versus the needs of developing economies. As noted previously, the US, the EU, Japan and other developed economies view the global IPR regime as an important component of international trade by providing legal security to

166 Okediji 2003b, pp. 335-336 and related footnotes.

167 Okediji 2003b, p. 329, footnote 51.

168 See among others, Bannerman 2009.

169 Muzaka 2011, pp. 34-35.

170 Muzaka 2011, p. 35.

their interests in order to defend their technologies against industrial competitors in emerging countries.[171] It is not their intention for trade agreements to have development as a priority (although certain development issues were considered during their drafting and ratification). The US, for example, as the prime mover of the TRIPS process has come under criticism for being able to "export" its IPR regime around the world because of its vast economic power.[172] Developing countries see themselves as having little say in how the standards are established but instead they are expected to "mechanically implement them at the national level as a trade-off for access to international markets."[173]

**Box I-11:** ***Need to Change National Law***

*International IPRs are the rules and regulations between several states whose individual national IPR regimes might be very different from each other. TRIPS was the product of a compromise between primarily developed countries with differing IPR systems. As a consequence, the terminology and concepts used by TRIPS may lack clear and comprehensive definitions as they were the product of the attempted consensus between developed states. The (IPR) interests of developing nations were not given sufficient weight. Furthermore, issues of special concern to African countries, such as biotech patenting, were not given sufficient consideration, as was the case with fundamentally differing views on 'property' in Africa as opposed to the US and the EU.[174] [175] The end result was that developing states were obligated to introduce foreign IPR systems whose design they were not part of.[176]*

*TRIPS is more specific than the Paris Convention in certain areas. For example, Article 27.1 requires that countries make patents available "for inventions, whether products or processes, in all fields of technology, provide that they are new, involve an inventive step and are capable of industrial application."[177] Countries are still permitted their own definitions of these terms and how the requirements of patentability are to be applied.[178] TRIPS remains silent on what constitutes an "invention." While there is some flexibility for Members to decide what*

171 Maskus 2009, p. 172.

172 Henry & Stiglitz 2010, p. 243 considers the US IPR regime "unbalanced".

173 de Carvalho 2005, p. 31.

174 Different views on property are discussed in a number of sources, a useful one is <http://www.wto.org/english/tratop_e/trips_e/trips_e.htm>, covering a number of relevant topics (accessed on 1 July 2011).

175 An example of an issue of special concern to developing countries is the so-called breeder's exemption in agriculture. Currently, plant material protected by patents – the rights' holders are usually situated in the "North" – cannot be used freely by plant breeders in the "South" for further breeder purposes and marketing. See Van der Kooij 2010, pp. 545-552, arguing for the introduction of a breeder's exemption in patent law, which he regards "TRIPS-proof". See also Part II.

176 See Hoekman & Kostecki 2009 (Chapter 8); Drahos & Mayne (eds.) 2002 (Chapters 1 and 10).

177 A footnote to Article 27.1 indicates that the terms "inventive step" (EPC) is synonymous with "non-obvious" (US) and "capable of industrial application" (EPC) with "useful" (US).

178 The term "all fields of technology" was held to include patents for pharmaceutical products (drugs). Many nations had only permitted process-related patents in the pharmaceutical area. These patents are much "weaker" than actual patents on the products themselves. Countries such as India had created an entire generic drug industry based on the lack of protection provided to pharmaceutical products. Uganda made provision for pharmaceutical patents in its 1991 legislation.

*constitutes an invention in their domestic law, the "definition must fall within the ball park area of things with practical or industrial utility."*[179] *As the debate over products containing genetic material (e.g., DNA sequences) has demonstrated, this is a wide ball park with "indistinct boundaries."*[180]

*In its submission on Article 27.3(b), the African Group stated that the patenting of life forms was contrary to the moral and cultural norms of many African countries. They recommended that 27.3(b) should be amended to exclude rather than include the micro-organisms, non-biological and microbiological processes that it requires to be considered as patentable subject matter.*[181] *The African Group further stressed that protection of plant varieties should not conflict with Members' right to pursue public policy goals related to food security and the elimination of poverty.*[182] *It is possible that countries seeking to exclude such inventions would have to utilize the morality exception of Article 27.2 ("to protect ordre public") or the general requirements for patentability. ARIPO and OAPI have permitted patenting of genetic material either through specific provisions or practice.*[183] *South Africa has implemented patent protection for biotechnology.*

*Regarding "new uses" for known products, TRIPS gives no guidance regarding the new or second use of patented products although analysis under the novelty requirement would normally prevent patent issue.*[184] *Different countries have adopted different approaches. For example, South Africa, Kenya and Uganda have all permitted second or new uses of products. In the case of South Africa a second medical use is specifically allowed.*[185] *Article 27.3(a) permits the exclusion of patents for "diagnostic, therapeutic, and surgical methods for the treatment of humans or animals."*

In the view of developed states, who seek "ever increasing levels of protection in foreign markets," the requirements of TRIPS constitute a baseline or "floor" on which additional IPR regulations should be added.[186] The term "TRIPS-plus" is applied to those agreements which pair (seemingly) attractive investment and trade conditions with "substantive regimes" of IPRs that exceed the essential TRIPS regulatory baseline.[187] Such agreements may be (bilateral, multilateral, or regional) free trade agreements (FTAs) or preferential trade agreements (PTAs).[188]

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179 Ong 2004, p. 36.

180 *Idem.*

181 WTO Paper IP/C/W/404 at p. 2. Referenced by Ong 2004, p. 112, footnote 161.

182 Ong 2004, p. 65.

183 See, generally, Thorpe 2002.

184 A number of European countries have managed by means of modifying both the "novelty" concept and claim construction to protect new and second uses (Thorpe 2002).

185 Deere 2009, p. 79, table 3.4.

186 Okediji 2003b, p. 338.

187 Okediji 2004, p. 128.

188 See, among others, Heath & Kamperman Sanders (eds.) 2007 on FTAs; Manger 2009; Hoekman & Kostecki 2009, Chapter 10 on PTAs.

**Box I-12: *Wider Impact of TRIPS-plus Agreements***

*Developing states are progressively more concerned about TRIPS-plus agreements imposed upon them.[189] For example, the UN Millennium Task Force on Trade notes that "(b)enefits may be limited (or achieved at the expense of others) but costs can be high. Unlike at the WTO where developing countries can form effective coalitions, in free trade agreements (FTAs) they are at a disadvantage in resisting the inclusion of nontrade issues or erosion of their WTO rights (such as TRIPS+ on patents, especially pharmaceutical patents, and other WTO+ provisions). Multiple FTAs with differing rules of origin impose high transaction costs, particularly on small traders, and divert the limited negotiating resources of poor countries from the pursuit of multilateral liberalization."[190]*

*In addition, states not directly involved in the negotiating and signing of individual specific Agreements, because of treaties with one of the signatories, may find themselves obligated to them. This is one effect of the "Most-Favored-Nation" clause in TRIPS which requires that "any advantage, favor, privilege or immunity granted by a Member to the Nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members."[191] As a result of this, the requirements of the TRIPS-plus agreements can impact states that were not even signatories to the original agreement with further implications in terms of capacity and resources - an example of TRIPS-plus implementation problems.*

TRIPS-plus agreements, so-called because they increase the IPR threshold above the minimal requirements of TRIPS, include treaties such as Preferential Trade Agreements (PTAs). Statistics show that at the end of 2007 the number of PTAs in force was close to 200 worldwide.[192] European countries account for most PTAs still in force, with the EU as the largest regional grouping. Contrary to PTAs among industrialized countries, PTAs between developed and developing countries are "nonreciprocal".[193] The popularity of PTAs is that bilateral agreements are effective policy tools – easier and quicker than reaching international consensus and including more favorable terms including, but not necessarily limited to, IPR rules.[194] Empirical evidence of what PTAs actually achieve beyond this is scarce.[195]

One concern is that TRIPS-plus trade agreements, by raising the level of IPR protection and enforcement, create realities that may at some point force WTO and WIPO to follow with similarly high international standards.[196] Another concern is that TRIPS-plus trade agreements limit developing countries in their trade choices. For example, the trade deal may only concern a sector or product that is of particular interest to the developed country – bananas for example, one of the best selling agricultural products in developed-country markets (see Box I-13).

189 See, generally, Stiglitz 2006; Gervais 2007a.

190 UNDP 2005, p. 7.

191 TRIPS, Article 4, Most-Favoured-Nation Treatment.

192 Manger 2009, p. 1; Hoekman & Kostecki 2009, p. 475, fig. 10.1, reporting WTO statistical numbers.

193 Hoekman & Kostecki 2009, pp. 474 and 532 ff.

194 Hoekman & Kostecki 2009, p. 479 explain in more detail why countries go preferential. See also explanation of popularity of PTAs by Manger 2009, pp. 220-238.

195 See assessment by Hoekman & Kostecki 2009, p. 508; and the findings of Manger 2009, pp. 221-238.

196 Gervais 2007a, pp. 26-27.

**Box I-13:** ***Effects of Imposing TRIPS and "TRIPS-plus" Requirements on Least-Developed States***

*In TRIPS, least-developed countries were identified as having "special needs" that required "maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base," something that was essentially non-existent in these countries and unlikely to develop unaided. Even in those cases where national IPR infrastructures are in the process of development, they are already heavily impacted by a new generation of "TRIPS-plus" standards enforced by bilateral trade agreements and economic partnerships (usually to benefit the developed country).[197] These standards require, for example, African countries to adopt far-reaching enforcement measures against parallel importation, counterfeit products and provisional measures that require authorities to operate on the behalf of IP right-holders – who are mostly based in industrialized countries. If they were more united and prepared to act in concert, for example via their membership in African-regional networks, they could strengthen their positions and help broker better terms.*

## 3.4 Undelivered Promises and Burdens of TRIPS

By their accession to TRIPS, developing countries sought to mitigate the controls of the Paris and Berne Conventions by "lower and more flexible standards of intellectual property protection, both domestically and internationally."[198] Regarding the use of GATT negotiations by developed countries:

"There was an assumption that, unlike WIPO negotiations where countries had to consider only the direct arguments for and against higher standards of protection, the GATT negotiations would force developing countries to offer concessions on IPRs in exchange for what they might gain in other fields (e.g., agriculture, textiles, and tropical products). An additional appeal of the GATT forum for the developed countries consisted in the opportunity it provided for effective enforcement of agreements and for dispute settlement mechanisms, both of which were practically lacking in the WIPO-administered conventions."[199]

However, the final agreement was quite different from what they had hoped as TRIPS has resulted in a "de facto adherence" to the Paris and Berne Conventions.[200] More than that, TRIPS can better be thought of as a "Berne and Paris plus" agreement as it not only incorporated elements of both but also added further requirements and enhanced enforcement measures.[201] The failure of the gains promised by TRIPS, the manner in which

197 Stiglitz 2006, at p. 104, mentions as an example of imposed TRIPS-plus obligations that in preparing the bilateral agreement between the US and Morocco "there wasn't much negotiations involved", and that "the US negotiators were mostly interested in having their way – and they wanted the new agreement to protect US drugs companies." Referenced by Gervais 2007a, pp. 26-27.

198 Correa & Yusuf (ed.) 2008, p. 7.

199 Correa & Yusuf (ed.) 2008, p. 9.

200 Gana 1996, p. 774.

201 Claessens 2009, p. 115.

TRIPS was imposed upon them and, in fact, the entire history of colonialism, produced resentment and suspicion among developing states.[202]

In contrast to other major agreements in the field of IPRs, such as the Paris or Berne Conventions, being a Member of the WTO and subscribing to TRIPS has meant "a considerable erosion of national sovereignty" due to countries having "lost the freedom to establish criteria for protection" (see Box I-14).[203]

The "higher standards of patent protection" reluctantly accepted by developing countries was no more than a "trade-off" that merely offered, in exchange for their acceptance, a lowering of tariffs on their exports to developed countries.[204] The TRIPS Agreement was never intended to be a one-way ticket to achieve developed status.

**Box I-14:** ***IPRs in Developed States***

*The expectations of developed states regarding the implementation of TRIPS-based IPRs by developing nations were inconsistent with their own history which had seen a long development of national IPRs. National IPRs, considered fundamental to a state's economy and development, cannot be merely "rubber-stamped." The action of European and North-American developed countries, in pressurizing developing states to "fast-track" the introduction of intellectual property rules according to updated international standards was contrary to their own early industrialization experience. In fact, developed countries required "over two centuries to design, experiment with and progressively institute national intellectual property systems", while developing countries for the most part were required to absorb foreign-imposed intellectual property systems" both during and after the end of colonial rule. [205]*

Successful implementation of TRIPS requires a country to have a functioning government infrastructure including legislative, administrative and judicial components capable of dealing with the complexities of modern IPRs. Both developing and least developed countries experienced "a very long and painful process" of implementation of the TRIPS requirements.[206] Their governments had to consider "diverse and complex" concepts that were often unfamiliar particularly to "civil servants, judges and law enforcement officials."[207] Additionally, political opposition challenged the approval of certain obligations, a notable example being the protection of micro-organisms and plant varieties as required by Article 27.3(b).[208]

TRIPS is not a self-executing treaty. This means that WTO Members have to implement the minimum standards and significant enforcement provisions required by the Agreement either by introducing new domestic legislation or modifying existing IP legislation. Necessary changes might involve an increase in scope (e.g., include pharmaceuticals), increase the

202 Gervais 2007a, pp. 5-17 detailing various TRIPS negotiating narratives, referencing among others the work of Yu 2005. See also, generally, Okediji 2003a, Okediji 2003b, Correa & Yusuf 2008.

203 Claessens 2009, p. 549.

204 de Carvalho p. 52.

205 Li & Correa (eds.) 2009, p. 5.

206 de Carvalho 2005, p. 67.

207 *Idem.*

208 de Carvalho 2005, p. 67.

duration of protection and even expand geographical coverage.[209] Important in the implementation of TRIPS is that "national law must provide for security" in that there are "no doubts about which rights are available to private parties, about how to obtain those rights and how to enforce them" (see Box I-15).[210]

Thus, while TRIPS has achieved some success in the standardization of international IPRs, it has also created problems for developing states which have been forced into accepting a system for which they are not ready. As noted in the Preamble to TRIPS, an important goal is to "reduce distortions and impediments to international trade" while promoting "effective and adequate protection of intellectual property rights." Unfortunately, developed states tend to forget another part of the Preamble, that the requirement of ensuring that the "measures and procedures" enforcing IPRs "do not themselves become barriers to legitimate trade."[211]

**Box I-15: *Promises of TRIPS***

*Article 67 TRIPS offers general assistance with TRIPS implementation to developing countries including "assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights."[212] Such assistance is usually not part of "TRIPS-plus" agreements although when incorporated into these agreements usually focuses on agreement-specific aspects of IPRs. Other concessions to developing countries such as those found, for example, in Paragraphs 5 and 6 of the TRIPS Preamble ("developmental and technological objectives" and "to create a sound and viable technological base") and paragraph 19 of the Doha Ministerial Declaration ("the development dimension") offered the promise that by merely implementing the TRIPS obligations, developing and least-developed countries will virtually be guaranteed technological and economic development. Similarly, Article 7 arose out of a proposal presented by a group of developing countries to the Uruguay Round Negotiating Group hoping that IPRs could be used to stimulate technological development.[213] Article 7 states that IPRs "contribute to the promotion of technological innovation and to the transfer and dissemination of technology … in a manner conducive to social and economic welfare."[214] In the end, the promise of TRIPS and its progeny such as the Doha Declaration have proved illusory. In fact, notes the UNDP, "the failure to deliver a development-oriented Doha Round constitutes the most significant gap in formulating the Global Partnership for Development."[215]*

209 See, for example, Walker 2001, para. 5.

210 de Carvalho 2005, p. 66.

211 TRIPS, Preamble.

212 Article 67 TRIPS, Technical Cooperation. "In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favor of developing and least-developed country Members."

213 GATT document MTN.GNG/NG11/W/71, of 19 May 1990 referenced by de Carvalho 2005, p. 122, footnote 329.

214 Article 7 TRIPS.

215 UNDP 2010, p. 36.

### 3.5 Greater Independence of Developing States

Developing countries manifest different "values, organization, and heritage" when compared to developed states[216] Not surprisingly, developing states showed reluctance, if not deliberate resistance, to agree to higher standards of intellectual property protection and enforcement based on foreign concepts of private property ownership. The Commission on Intellectual Property Rights concluded that the use of "webs of coercion" by the United States and the European Union denied developing countries the power to meaningfully influence the international IPR negotiations and standard-setting.[217] In fact, in order to implement new legislation, or modifying existing legislation, countries were usually required to go beyond that which is required by TRIPS and "implement in their law more extensive protection."[218]

Over time, developing states began to act as a group in an effort to have a greater input on international IPR rule making.[219] Examples of the most important initiatives in this regard have been promulgated in the 2000s: the WTO Doha Declaration, the Declaration on TRIPS and Public Health, and the WIPO Development Agenda.[220]

In 2007, the Members of WIPO agreed to the "aim of placing development at the heart of the Organization's Work."[221] Part of the mandate of the Committee on Development and Intellectual Property (CDIP) created to implement the organization's recommendations included "discuss(ing) IP and development related issues."[222]

As regards the latter, in the course of the WIPO Development Agenda (2007) developed countries questioned the demands for broader, longer-term exceptions. In addition, demands by developing countries to include previously not recognized "traditional knowledge" (TK) and biodiversity in TRIPS are being met with resistance. This debate is ongoing and has not yet resulted in consistent changes to the global IPR regime (see Box I-16). Considering that firms in the "North" view IPRs as a means to defend their technologies from uncontrolled leakage to industrial competitors, an agreement by their governments to sign on the WIPO Development Agenda would only be accepted with resistance. For example, the US prefers a far stronger approach to harmonization, favoring a treaty under which each major patent office would harmonize its eligibility rules, examination procedures, approaches to claim construction, and processes for third-party registration. These proposals would exceed the minimum standards for patents in TRIPS but are consistent with US policy linking acceptance of international agreements such as the Development Agenda to its own national agenda.[223]

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216 Okediji 2003b, p. 354, discussing "the cultural narratives" related to the participation of developing countries in the IPR system.

217 Drahos 2002b.

218 Article 1.1 TRIPS.

219 Hoekman & Kostecki 2009, pp. 378-379, 390-391.

220 See on the WIPO Development Agenda: De Beer (ed.) 2009 and May 2009; WTO Development Agenda: Gervais (ed.) 2007; on WIPO's and WTO's Development Agenda: May 2009.

221 See, generally, <http://www.wipo.int/ip-development/en/agenda/> (accessed on 1 July 2011) .

222 For a complete list of the 45 Adopted Recommendations under the WIPO Development Agenda <http://www.wipo.int/ip-development/en/agenda/overview.html> (accessed on 1 July 2011).

223 Maskus 2009, p. 172.

**Box I-16: *Traditional Knowledge***

*Another side to the "Development Agenda" debate asks whether traditional knowledge (TK) can be viewed as intellectual property in the classic sense. Examples of "cultural knowledge to facilitate the innovative process" are well described.*[224] *There are several reasons why TK protection is in conflict with classic IPRs, not the least of which is the fact that TK generally fails to "meet the criteria for current forms of intellectual property."*[225] *Patents are awarded for "innovation" while TK represents knowledge that is acknowledged to be many generations old. Patents are applied for in the name of a specific inventor or group of inventors (of course they can later be assigned to a multinational). TK on the other hand is owned by the group, sometimes a designated group within a nation, such as the traditional healers. The other criteria generally accepted as necessary for the granting of a patent (novelty, non-obviousness and utility) are also not readily established for the products of TK. Significant also is that consistent with the underlying "contract" between society and the inventor, IPR-protected knowledge will enter the public domain to be accessed by all. By its nature, TK already exists in the public domain or, if limited to a small group, is restricted to members of that group for as long as the nation exists. At the core, modern international IPRs are incapable of protecting the "spiritual, religious or moral interests associated with traditional knowledge."*[226]

### 3.6 The Special Case of Compulsory Licensing

One of the consequences of the TRIPS Agreement was the "strong patent rights for pharmaceuticals … and the corresponding limited opportunities for developing countries to secure access to medicines."[227] One avenue remaining was the use of the compulsory license mechanism of Article 31.[228] However, these procedures are not easily utilized.[229] (See Box I-17).

For example, the patented invention cannot be used while the compulsory license application, which usually takes a long period, is being processed. The Paris Convention prevents a compulsory license being applied for on the grounds of failure to work or insufficient working until four years from the date of filing of the patent application or three years from the date of grant, whichever expires last. (Art. 5(A)(4) PC). Obviously, during the period of compulsory license application, the applicant cannot utilize the patented product as this would constitute infringement. Also significant is the potential loss of "goodwill" that usually results when a compulsory license application is made, the granting of which generally results in some loss of revenue for the patent holder. The implications of such an application can extend far beyond the immediate issue impacting on later trade negotiations.[230]

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224 Gana 1996, p. 751, describing such examples as the development of capsaicin cream as a result of observing the use of hot pepper by South American indigenous tribes and "d-tubocurarine", a muscle relaxant derived from an arrow poison used by Amazonian Indians.

225 Okediji 2003b, p. 354.

226 Okediji 2003b, p. 355.

227 Okediji 2003b, p. 345.

228 The term "compulsory license" does not appear in TRIPS. Rather, Article 31 TRIPS is entitled "Other uses without authorization of the right holder".

229 Van Zimmeren & Van Overwalle 2011, p. 20.

230 Van Zimmeren & Van Overwalle 2011, p 20.

Article 31 does provide a detailed list of the provisions under which these uses are permitted. For example, 31(b) requires that the proposed user has "made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." However, "in the case of a national emergency", "other circumstances of extreme urgency", or "in cases of public non-commercial use" the need to obtain such authorization can be waived.

**Box I-17: *Article 31 – "Other Use Without Authorization of the Right Holder" (Compulsory Licenses)***

*Compulsory licensing is a mechanism whereby a government allows someone other than the rights' holder to utilize or manufacture a patented product without the consent of the patent owner. Taken at face value, it appears that the compulsory licensing system incorporated into TRIPS can solve a major problem in the developing world by permitting states a mechanism whereby they can obtain cheap access to pharmaceuticals in cases of a national emergency. However, Articles 31(f) and (c) do not make this quite so simple. When a patented product is to be used "without the authorization of the right holder," 31(f) requires that such a use must be "authorized predominantly for the supply of the domestic market of the Member authorizing such a use." Article 31(c) requires that the "scope and duration" of the unauthorized use "shall be limited to the purpose for which it was authorized" meaning that the quantities of the patent-protected product produced under a compulsory license must be compatible with national demand in the country where it is produced. The consequence of 31(f) and (c) is such that a compulsory license whose purpose is to supply a foreign market cannot be granted.*[231] *The limitation inherent in Article 31, namely that a compulsory license is permitted for domestic use only, is the cause of "the main problem for developing countries lacking sufficient pharmaceutical manufacturing infrastructure and requesting to grant compulsory licenses to import generic versions of patented pharmaceuticals."*[232] *This means that even though a country that is faced by a public health emergency and it is ostensibly permitted by TRIPS to license a local manufacturer to produce the essential medicines, without an appropriate manufacturing infrastructure it remains powerless.*

From the onset, developing states were concerned that developed states would act to intimidate them and thereby prevent their use of the "flexibilities" built into TRIPS. Subsequent events proved these concerns justified as the legal right to use compulsory licensing to produce essential medications in times of national emergency has been resisted by developed states.[233] This stance has deprived developing states of an important means of making accessible expensive medications. The US, in order to protect its own industries, has been known to pressure countries that attempt to use flexibilities by, for example,

[231] Article 31(c): "the scope and duration of such use shall be limited to the purpose for which it was authorized." Article 31(f) "any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use."

[232] Weitsman 2006, p. 91.

[233] Henry & Stiglitz 2010, p. 244.

threatening to use, or actually using, its "301 Watch List" for countries that it sees as failing to provide adequate and effective IPR protection to US industries.[234]

Developed states themselves have not hesitated to take advantage of the TRIPS provisions and used compulsory licenses in a range of situations. The US, for example, has used its compulsory licensing power when threatened by an outbreak of anthrax, as a remedy for antitrust violations and to force private companies to make available patent protected inventions in the cause of national security.[235]

In principle, the compulsory license mechanism has some power.[236] In a few cases, merely the threat of a compulsory license has been enough to pressure companies to reduce their prices. For example, in 2005, China successfully obtained licenses for the manufacture of Tamiflu by threatening the patent holder with a compulsory license.[237] By means of a similar threat, in 2001 Brazil obtained lower prices for two HIV/AIDS drugs.[238]

But in reality, countries show reluctance. The issue is that the "flexibilities" are not easily implemented and therefore their use is discouraged. As an illustration, TRIPS laid out a series of procedural requirements for compulsory licenses which in effect limit - but not eliminate - their use, while in addition to this developing countries are reluctant to use this option for fear of sending negative signals to foreign investors about their commitment to protecting private property and the business environment more generally.[239]

In response to the limitations placed on the award of a compulsory license under the TRIPS regime, developing countries have attempted to rectify on this aspect of TRIPS. To this end, the Fourth Ministerial Conference in Doha, Qatar in 2001, one goal of which was to solve the problem of access to drugs, adopted the "Declaration on TRIPS and Public Health" (The Doha Declaration). The Conference recommended (Doha Clause 19), based on a review of TRIPS 27.3(b), that the Council should be guided by Article 7 (the facilitation and dissemination of technology)[240] and Article 8 (protection of public health and nutrition).[241] (See Box I-18).

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234 The "301 Watch List" refers to the amended Section 301 of the US Trade Act of 1974. Placing a country on the watch list can lead to trade sanctions. Compliance with TRIPS does not preclude a country from being identified as denying "adequate and effective protection of intellectual property rights", writes J.T. Masterson, *International trademarks and copyright: enforcement and management,* American Bar Association 2004, pp. 18-20.

235 Henry & Stiglitz 2010, p. 245.

236 Cottier 2006, pp. 13-15 is referenced here for the EU context. Cottier observes that the law of compulsory licensing of IPRs "is not clearly settled and may vary from case to case" (p. 13). Importantly, in the *Magill* case (1995) before the European Court of Justice, a compulsory license was granted to create a new product – a weekly TV guide – not available otherwise under monopoly structures; see joined Cases C-241/91 P and C-242/91 P, *RTE and ITP v. Commission*, 1995, ECR I-743, under 46-58 ("an abuse of a dominant position"). The Netherlands has not issued compulsory licenses, according to a spokesman of the then-Ministry of Economic Affairs, in early 2010; it does not see much potential because of the required payment to the rights' holder.

237 Deere 2009, p. 230.

238 Deere 2009, p. 230. See also Chapter 4, para. 4.6.

239 Muzaka 2011, p. 36.

240 Article 7 TRIPS, Objectives. "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

**Box I-18:** ***Doha Declaration – Insufficient Manufacturing Capability (the "Paragraph 6 Problem")***

*One significant problem acknowledged in paragraph 6 of The Doha Declaration was "that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement." In order to solve this infrastructure problem, the EC suggested that a compulsory license to manufacture a drug granted by a country without the necessary manufacturing infrastructure should be "recognized" by another country making it possible to supply the state issuing a compulsory license the medication.[242] The Council was instructed to determine "an expeditious solution" to this particular problem before the end of 2002. Following a great deal of discussion, the WTO General Council Decision of August 30, 2003 ("The Decision") permitted an interim waiver of Article 31(f).[243] The waiver would permit the exportation of medicines produced under a compulsory license to those countries that lacked sufficient manufacturing infrastructure to produce these medicines for themselves. Implicit in The Decision is that the compulsory exporting license is only available when the products are not available on the international market. The Decision also provides for a permanent amendment to the TRIPS Agreement once ratified by the required number of WTO Members.*

In the short term, the Doha Conference goal was that developing states "were able to present carefully developed, specific proposals that could be accommodated in WTO rule-making."[244] In the long term however, the solution to paragraph 6 of the Doha Declaration on TRIPS and Public Health has not been supported by the necessary two-thirds of the WTO member states and the current TRIPS provision on compulsory licensing remains unchanged. Thus, the waiver formulated in the Doha Declaration of 2001 that would permit the exportation of medicines produced under a compulsory license to those countries that lacked sufficient manufacturing infrastructure to produce these medicines for themselves, awaits endorsement as a permanent amendment.

## 3.7 Conclusion

The history of IPRs can be characterized as an "unbroken historical chain lasting more than five hundred years."[245] Generally, this has been for the benefit of the European colonial

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241 Article 8 TRIPS, Principles, 1. "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

242 Communication from the European Communities and their Member States, WTO document IP/C/W/280, of June 12, 2001. Referenced by de Carvalho 2005, p. 331, footnote 870.

243 Article 31: "Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder … the following provisions shall be respected: … (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;"

244 Thorpe 2002, p.164.

245 Okediji 2003b, p 384.

powers who have used IPRs, "an entrenched feature of international economic relations," as a means to "control competition from former colonies."[246]

Sadly, this "long historical chain," with regard to developing countries does not seem to have changed the "low levels of domestic innovative activity in most of these countries."[247] Not only are the "overwhelming majority of patents granted by developing countries … granted to foreigners", but also "very few inventions are made by the nationals of developing countries."[248]

The success of TRIPS and related IPR treaties remains a question particularly in terms of the benefits to development.

"A number of recent studies offer a blurred and complex picture of the advantages of (high) IP protection in developing economies. It now seems clear that since TRIPS was informed more by the belief that introducing "Western" IP norms would induce development than by actual supporting analysis and data, TRIPS put the policy cart before the empirical horse. We now know that a simple equation cannot be drawn between an increase in trade following the introduction of TRIPS-compatible IP protection, on the one hand, and economic development on the other, especially when measured in terms of welfare increases."[249]

The TRIPS agreement did achieve some successes with a new regime of increased global IP protection which included an enforcement mechanism and "a meaningful shift to substantive harmonization in various aspects of intellectual property protection."[250] However, despite this promise, the HIV/AIDS crisis in Sub-Saharan Africa with its attendant concerns about the role of intellectual property protection in the cost of anti-retroviral medications has raised significant concerns about the "legitimacy and success" of the TRIPS Agreement.[251]

IPRs are national in application and to make them universally meaningful requires an international agreement that serves to both standardize their rules and create a mechanism whereby they can be enforced for the benefit of all international trading partners. Developed states, which were becoming increasingly concerned at the threat to their intellectual property, by using the GATT process, negotiated TRIPS to achieve these dual goals of harmonization and enforcement power.

This process unfortunately took its toll on their relationship, already soured by the history of colonialism, with the developing world. Using a "carrot and stick" approach, developed states sought to compel membership of the WTO and acceptance of TRIPS. In order to be TRIPS compliant, and later TRIPS-plus compliant, developing states had to modify, and in some cases significantly alter their legislation, legal systems and IPR-administration often without receiving the benefits promised by the "carrots."

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246 Okediji 2003b, p 335. While the point is clear, about 50 years after independence of African countries it is difficult to still speak of "colonialism" (compare Calderisi 2007, p. 22).

247 Okediji 2003b, p. 339.

248 Okediji 2003b, p. 339, footnote 91, referencing A. Samuel Oddi, 'The International Patent System and Third World Development: Reality or Myth?' (1987) *Duke L.J.* pp. 831, 843-44.

249 Gervais 2007a, p. 28.

250 Okediji 2003b, p. 315, footnote 1.

251 Okediji 2003b, p. 340.

In order to achieve MDG targets, certain strategies are necessary including encouraging and supporting development and effective governance nationally and ensuring a viable global partnership that can create an enabling environment for the MDGs.

Essentially this would require greater cooperation between developed and developing states. For example, given that many developing countries do not have sufficient background and experience to meaningfully participate at the level of international policy and rule-making meetings, developed states should ensure financial support and education of policy-makers and representatives of developing countries.

Beginning with the methods of IPR negotiation, there should be less of the imposition of IPRs witnessed earlier but rather a mutually acceptable negotiation process taking into account the disparate needs of each party. Intellectual property, often produced at great expense and requiring highly advanced technology to develop, must be respected while at the same time concessions can be made for developing needs. An example of an area that holds promise in this regard, is the compulsory licensing system, which could provide a means of supplying cheap generics where needed most, while at the same time protecting patented product in markets where it can be afforded. However, as will be detailed in Chapter 4, having the power to impose a compulsory license does not necessarily solve a country's problem of access, as without "the technical capacity and coordination to turn their initial grant of a compulsory license into a practical outcome" (i.e., without the necessary infrastructure), the compulsory licensing mechanism is valueless.[252]

At the same time, the post-TRIPS use of bilateral and regional agreements is seen as a "means to roll back both substantive and strategic gains" from TRIPS at the "expense of developing countries."[253]

As noted in the TRIPS Preamble, a goal of the Agreement is to "reduce distortions and impediments to international trade" while promoting "effective and adequate protection of intellectual property rights" and ensuring that the "measures and procedures" enforcing IPRs "do not themselves become barriers to legitimate trade."[254] Whether the issue is one of standardization of national IPR systems or the legitimate enforcement of rules, greater emphasis should be given to a global partnership that can create an enabling environment for the MDGs. In a similar vein, it is possible that the "inherent elasticity in intellectual property categories" may make it possible for some of the products of TK to be incorporated into the modern international IPR system.[255]

Concerns about the impact of international IPRs and their effects on developing nations have raised the question of a role for human rights doctrines.[256] The interaction between human rights and IPRs has been framed "in terms of how human rights might be used as a countervailing force against intellectual property rights."[257] The balance is complex: too little protection and the incentive to innovate is diminished, while too much protection will

252 Deere 2009, p. 231.

253 Okediji 2004, p. 129.

254 Preamble to the TRIPS Agreement.

255 Okediji 2003b, p. 337.

256 There is a collection of sources on human rights' approaches to IPRs and the international IPR system. Recent (hot-off-the-press) publications include: Kur (ed.) 2011; Matthews 2011: Helfer & Austin 2011; Grosheide (ed.) 2010. The human rights' perspective is not explored in this report.

257 Okediji 2003b, p. 346.

"undermine fundamental human rights."[258] The human rights "approach" to analysis of TRIPS does not appear to negate the right of an inventor to benefit from the "fruit of creative endeavors" but rather address the "imbalance between owners of knowledge products and users of such products."[259] The issue for the future is whether IPRs can "ever truly be reconciled with the core principals of international human rights law" and, if so, how this would impact modern international IP law.

Consideration must be given to modifying the international IPR system – essentially European and American in its construct – to take into account the specific needs of developing countries. Consideration could be given to such mechanisms as a "fair use" model possibly consistent with the "fair use" available under US copyright law, and the use of a form of "open source" in patenting and patent pools. This would require virtually a reevaluation of the essential nature of patent rights. IPRs are not the whole solution to solving the problems of providing for public welfare. The debate about the system, and in fact the entire role of IPRs, must extend "beyond the experience of developed countries."[260]

[258] Okediji 2003b, p. 346, footnote 116, referencing Haochen Sun, 'A Wider Access to Patented Drugs under the TRIPS Agreement', *Boston University International Law Journal* Vol. 21 (2003), pp. 101 ff, at p. 136.

[259] Okediji 2003b, p. 347.

[260] Okediji 2003b, p. 385.

# Chapter 4 INFRASTRUCTURE

## 4.1.1 Introduction

> "Sufficient and adequate intellectual property protection is but one ingredient in a complex recipe to achieve innovation-based economic development."[261]

IPRs cannot be regarded in isolation. Rather, the context and circumstances of developing countries including economic development and its social dimension require a more comprehensive evaluation, as will be illustrated in this Chapter. Consistent with the remainder of this report, this Chapter will primarily focus on patents. Further, while this Chapter will be discussing patents mostly, it will often follow the broader discourse and speak of IPRs.

## 4.1.2 Building Blocks and Process of Organizational Change

In addition to the policy-oriented view of development (MDGs) utilized in this report, particularly relevant to this section is to consider development as an enduring process of organizational change.[262] Organizational change includes setting up, expanding and improving the essential "building-blocks" of the infrastructure of a modern state. These building blocks are both physical – e.g., roads, electricity and hospital buildings – and institutional – e.g., government institutions, financial system, markets.[263] The process of organizational change is shaped by human, natural and financial resources, available technology and skills, the nature of a particular government and its methods of governance, national history and traditions, the role of existing institutions (whether positive or negative), and distribution of wealth.[264] Unfortunately, in developing countries the presence of positive "building-blocks" cannot be taken for granted.

In light of the requirements for successful organizational change, the role of an IPR regime in the poorest countries remains an issue. First of all, the basic physical infrastructure is often deficient.[265] As the MDG Africa Steering Group concluded in 2008, the lack of transport, power, communication networks, water, sanitation and other infrastructure services poses severe constraints on economic growth, trade and poverty reduction across Africa. For example, regarding electricity supply, the Group reported 35 African countries experiencing frequent supply interruptions, and, considering the entire continent overall, only one in four Africans has access to electricity, dropping to one in ten in rural areas.[266] Second, countries need a certain level of institutional sophistication to be able to successfully cope with a modern IPR regime. Depending on where they are in the process of organizational

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261 Gervais (ed.) 2007, p. 45. At this point it will be assumed that innovation (see para. 4.2) can be instrumental to growth in developing countries.

262 Chapter 1, para. 1.2.3. Banji & Padmashree 2010, p. 5.

263 See Chapter 1, para. 1.2.8. Extensively on infrastructure: Banji & Padmashree 2010, Calderisi 2007 throughout their book; Hoekman & Kostecki 2009, pp. 386-387, 396, 464, 551, 565.

264 Adapted from Banji & Padmashree 2010, p. 5.

265 See Chapter 1, para. 1.2.8.

266 MDG Africa Steering Group 2008, p. 16.

change and the status of their infrastructure, developing countries likely face a deficiency in their ability to support a functioning national IPR system.

Merely incorporating international IPR standards into a nation's legislation is insufficient; adequate implementation via a successful infrastructure is needed to make the legislation work. This means having a viable legal and enforcement system comprising a legislature including policy-makers, judges capable of dealing with complex litigation, a competent patent office with trained examiners and research capabilities, sophisticated police and customs agents able to enforce IPR legislation and legal judgments, and other institutions involved in the execution of national laws and policies. In addition to the "public sector infrastructure," a "private sector infrastructure" is necessary, comprising manufacturing industries and their associated components.[267]

Essentially, countries in Sub-Saharan Africa,

> "lack the essential capacity and/or will to fulfill four sets of critical government responsibilities: fostering an environment conducive to sustainable and equitable economic growth; establishing and maintaining legitimate transparent, and accountable political institutions; securing their populations from violent conflict and controlling their territory; and meeting the basic human needs of their population".[268]

At the time of the standard-setting TRIPS Agreement (1994), almost none of the countries in Sub-Saharan Africa had the kind of sophisticated IPR infrastructure that TRIPS requires. Further, the international IPR regime is about *trade* and not *development*. From the point of view of developing countries this is unfortunate as their development needs are great – hence the MDGs – while their ability to participate in global markets are small. As it has been observed:

> "After (…) decades of experimenting with Western-styled intellectual property laws and an inordinate emphasis on technology from developed countries as an agent of development, African countries remain mired in trenches of underdevelopment."[269]

### 4.2 IPRs Part of Innovation Policy

What is required in terms of capacity and capability for developing countries to design and benefit from an IPR system, is extensive. Given the need to prioritize, it is important to determine the specific capacity-building[270] or resource needs that should take priority. In essence, developing countries need to design a local policy for economic growth with the aim of improving how the local market functions in addition to introducing options for local innovation. In cases where TRIPS-compliant laws were drafted before appropriate policies directed at local circumstances were developed, this has to be in effect reversed and attention paid to creating systems based on the local circumstances.

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267 *GIZ* 2010. Pharmaceutical companies in certain African countries are able to produce medicines for their domestic markets however the active pharmaceutical ingredients are generally imported from India.

268 S.E. Rice & S. Patrick, 'Index of state weakness in the developing world', report Brookings Institution 2008, as cited by Mbeki 2009, p. 153.

269 Okediji 1996, p. 315.

270 See definition in Chapter 1, para. 1.2.8.

Innovation[271] can be both technological – applied science for everyday problems, for example – or social – such as improved work methods and management.[272] Regardless of the kind of innovation in question, developing countries could benefit from the transfer of knowledge not only from developed countries but also from within their region, in our case, Sub-Saharan Africa. This means of course that a necessary underlying prerequisite for supporting policies and their implementation are local human resources and institutions as part of the package needed to develop an innovation system.[273]

It is within this context that IPRs, as potential tools to promote innovation, should act to support local inventors to innovate, protect, develop and exploit their inventions.

## 4.3 Implementation of IPR law

### 4.3.1 Importance of Viable Infrastructure Recognized in TRIPS

Implementation of IPR policy and legislation – and fostering growth from innovation more broadly – cannot be considered in isolation particularly if other essential components are not in place. This is a danger in Sub-Saharan Africa where, as noted in other regions, countries have often introduced the legislation to become TRIPS compliant, only to later find out that a lot more is required for a functioning IPR system.

The importance of a viable infrastructure was recognized in Article 67 TRIPS which requires that developed countries assist developing and least-developed member states with TRIPS implementation in the areas of legislative assistance, capacity building (e.g., training of judges and law enforcement agencies) and institution building (e.g., modernizing patent offices). Despite this promise, many African countries do not yet have functioning IPR systems comparable to those of developed states or, at least, able to cope with the requirements of the world of modern intellectual property. A lack of adequate infrastructure prevents full implementation of TRIPS beyond the legislative stage - the relevant laws have been passed but full implementation has been blocked by a lack of both the building blocks and the functional components of a viable infrastructure. Successful implementation of IPR law, rather, requires "a combination of factors, including health funding, political commitment, and flexibility." [274] Merely instituting intellectual property protection domestically or internationally does not guarantee robust development: with the introduction of IPRs, trade might be enhanced in "middle-income and large developing countries but not among poor countries," as they lack industry, patentable inventions and innovation.[275]

A question is whether developing countries will be better off if they imitate the systems, including institutions for supporting IPRs, of the "North", or rather innovate and design an original system that better fits with their needs. A recent study on India has touched upon this question without reaching a clear generally-applicable conclusion but noting that "(f)rom either point of view, a better understanding of whether innovation or imitation is occurring in practice is important for assessing the costs and benefits of TRIPS."[276] An important,

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271 *Idem.*

272 Adapted from Van Casteren 2011, p. 9.

273 Gervais 2007a, p. 45.

274 Kettler & Collins 2002, p. 6.

275 Claessens 2009, p. 533.

276 Sampat 2010, p. 31.

empirical question in this regard is whether in developing countries that have implemented TRIPS, the implementation has resulted in more patenting by locals (an indicator of local innovation). A recent comparative study has found support for the common assumption that once a country is on the threshold of becoming developed (in terms of the gap in income vis-à-vis the developed world), strong IPR protection becomes advantageous.[277] As other research has shown, such "frontier economies" are characterized by "high science-intensive and technology-intensive activities, with relatively high levels of domestic investment in R&D."[278] Countries tend to strengthen IPR protection over their development stages, as was shown by analyzing present developing countries at various stages but also "early-developing" countries such as European countries.[279]

The presence of a functioning IPR system is often believed to be of importance to corporations engaged in international trade. The comparative study just mentioned has found that even though some multinationals may not invest in a developing country if IPR protection is not there, there is not a universally confirmed effect. In fact, "IPR may be irrelevant for investment into countries at the primitive stage of catch-up and with limited technological capabilities."[280] The study's data further suggest that countries had various ways of access to new technologies and knowledge, for example by importing machines and commodities not protected by patents, which they used and learned from.[281]

### 4.3.2 Functioning Institutions Such as Judiciary

Other factors such as "differences in depth of government expertise on IPR issues, the administrative competence of government institutions, and the ability to maintain control of national IP offices" impact IPR implementation.[282] It stands to reason that a developing country may be faced with not only a lack of the needed science and technology skills but in addition needs institutions not only capable of "harnessing its indigenous knowledge to the goals of development" but also capable of "mediating new knowledge from outside its borders".[283]

Furthermore, for an IPR system to be meaningful, rights holders must be able to rely on national authorities, such as the judiciary or the customs system, if their rights are infringed. Judges, legal practitioners and civil servants must be capable of handling complex patent litigation whose resolution often requires a detailed understanding of a patent's underlying science. Therefore, not only must they have the appropriate legal background, but also sufficient education to understand complex science and technology. The system must provide them with access to research, up-to-date databases and competent experts to advise them. In addition, there is a need for qualified patent examiners, who must search prior art

277 Odagiri *et. al* (eds.) 2010, p. 424. Catch-up is described as narrowing the gap in income vis-à-vis a leading country, p. 2.

278 Banji & Padmashree 2010, p. 74.

279 See for the complexities of this finding, Odagiri *et. al* (eds.) 2010, pp. 425-426. The study categorized countries for research purposes into developed ("early developing") countries, "post-World War II" countries, Latin America and Asia; Africa is not included.

280 Odagiri *et. al* (eds.) 2010, p. 420.

281 *Idem.*

282 *CIPR* 2002 as cited by Deere 2009, p. 197.

283 Banji & Padmashree 2010, p. 11.

and examine new patents according to the strict rules of "patentability," to handle a volume of patent applications and deal with advanced subject matter.[284]

## 4.4 Myths about International IPRs (mostly patent-related)

### 4.4.1 Myth: "IPRs have a natural (strong) form"

This section seeks to counter certain myths – or overstated qualities – about IPRs in general but particularly in regard to patents.

The design (or "form") of a nation's intellectual property, perhaps like real property, reflects conceptual choices as to scope and ownership.

> "Property rights have no ideal form which could be rendered clear and strong. Their allocation is everywhere a matter of economic, social and political choice for which no formula can substitute. (…) The definition of "ownership" requires a strategic idea about use. Different decisions about the allocation of entitlements and the meaning of ownership may lead to different development paths … The call for clear property rights obscures the range of alternative property regimes which have always been at work within the industrialized West, reflecting different resolutions to the management of social/economic/political conflicts. (..) A property regime, like any other legal order, is all about choices."[285]

Developing countries are faced with IPR concepts that were constructed, sometimes over a period of centuries, in the "North". Nevertheless, and despite the pressure to create a TRIPS compliant domestic IPR regime, local policy-makers in developing countries should make choices relevant to their own situation.

### 4.4.2 Myth: "Presence of IPRs ensures that system functions as intended"

Contrary to what is often believed (or perhaps hoped), the mere presence of IPRs does not necessarily mean that the system will function as intended. The reality is that infrastructure is a functional system of three interrelated but separate components consisting of (1) laws, (2) practices and (3) institutions. This can explain "how IP affects knowledge production, sharing and use within biotechnology innovation systems."[286]

Therefore, having patents on technology will not always defend against possible infringing uses such the "practice" of companies (the "institution") to permit scientists to research for commercial purposes the patented inventions of a competitor, choosing to ignore the "letter of the law," i.e., whether they are in fact infringing the patent. In another scenario, the high cost of litigation may prevent a company suing an alleged infringer to defend its patent.

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284 ICTSD & UNCTAD 2003, p. 49.

285 Kennedy 2011, pp. 53-54.

286 Gold 2008, p. 22

### 4.4.3 Myth: "Strong IPRs ensure innovation and growth"

In theory, the successful introduction of patent rights in developing countries allows the system to "establish confidence in foreign technology holders and convince them to license inventions under competitive conditions," "generate efficiency in metering imported inventions" and "contribute to general legal certainty, hence economic efficiency."[287] Stronger patent protection, it is hoped, will encourage technology transfer as rights holders are reassured that the country receiving patent-protected technology will enforce the owners' patents. In particular, this "legal certainty" will reduce the cost of performance guarantees usually required from licensees and ultimately thereby reduce technology prices.[288]

But it does not seem to work quite in this way, particularly in many countries in the "South". Contrary to the hopes of many developing countries, the introduction of strong IPRs did not automatically produce innovation and economic growth. A multiple-country analysis (2009-2010) into whether stronger patent rights achieved their intended objective of stimulating economic growth actually showed no conclusive benefit from having strong IPRs commenting that "(t)o the best of our knowledge, to date, there is no robust empirical evidence that stronger patent rights indeed stimulate growth (..)."[289] This finding is supported by studies over a longer period (see Box I-19).[290]

It is generally accepted by proponents of IPRs that, by producing legal security and predictability, they provide for reduced transaction costs and thereby encourage entrepreneurs to invest in R&D.[291] But without a functional legal and social infrastructure including "social and political stability, a reliable court system and a free market environment," IPRs will not provide the hoped-for economic and innovative outcomes.[292] Factors considered important to achieve this goal, probably even more significant than IPRs themselves, include being the first to enter a market, differential tax rates for national and foreign companies, income tax credits for R&D, special rules that apply to agricultural biotechnology products, and regulatory rules regarding new medicines.[293] Without the appropriate infrastructure, a frequent deficiency in developing states, neither development and innovation nor attaining the MDG goals will be possible.

**Box I-19:** ***Relationship between IPRs, Local Economic Factors and R&D***

*A 1997 paper studying the relationship between IPRs and economic growth for a cross-section of countries for the period 1960-1990 found interesting results that were later confirmed by others.*[294] *"The results also show that, while R&D is an important determinant of developed and*

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287 de Carvalho 2005, p. 54.

288 de Carvalho 2005, p. 127.

289 Hu & Png 2010, p. 25.

290 Park & Ginarte 1997; referenced by Wong & Dutfield (eds.) 2011, p. 3 with mention of other studies. See also Boldrin & Levine 2008, p. 187, with footnote 4, who write that the historical evidence of industrialized countries provides little or no support for the view that an IPR is an effective method of increasing innovation.

291 de Carvalho 2005, p. 126.

292 *Idem.*

293 McGill 2008, p. 18.

294 Park & Ginarte 1997, pp. 51-61.

*developing country growth rates, IPRs matter for the R&D activities of the developed economies but not for those of the less developed economies. This suggests that, for the latter group of economies, either their R&D responds to different incentives (such as cultural rewards) or a significant part of their R&D activity is imitation. The results have some implications for policy at the international coordination level. First, as countries develop and switch from imitative to innovative R&D, they are more likely to be interested in promoting stronger intellectual property protection (…). Second, it is important to understand that institutions are not created in a vacuum. Institutions, such as an intellectual property rights regime, are costly to create and maintain. Their emergence is likely to depend on whether the incentives are right – that is, whether the benefits outweigh the costs. In this case, the returns to an IPR regime are larger the greater the intensity of (innovative) R&D activity. (…) Likewise, an intellectual property regime requires resources for its creation and enforcement and also exacts welfare and other losses resulting from the granting of temporary market power. In order for an investment in this institution to be worthwhile, the benefits – in the form of new knowledge and improved macroeconomic performance – must exceed those costs. The benefits or returns are larger in economies with a stronger innovative research sector. On the other hand, innovative R&D takes place under conditions in which intellectual property rights are well protected and enforced."*[295]

To further counter the myth that strong IPRs ensure innovation and growth, one African study is mentioned here. Looking at the impact of IPRs on economic growth for a cross-section of 34 Sub-Saharan countries from 1985 to 2003, and using three different estimation techniques, the results of the study indicate that: (1) strengthening IPRs has a negative effect on economic growth; (2) domestic investment is positively correlated with economic growth; and (3) human capital is an important determinant of economic growth.[296] The negative effect of IPRs on economic growth might suggest that most innovation in SSA may be imitative or adaptive in nature.[297] The findings provide support for the assumption that a "one size fits all" approach to harmonizing IPRs in developing countries will not produce the expected benefits for Sub-Saharan African countries.

### 4.4.4 Myth: "Universal 'incentive effect' of patents"

Developing countries have been encouraged, or induced, to introduce complex IPRs based on promises of easier access to the markets of developed countries and the hope that IPRs will lead to greater domestic innovation and financial reward. But the promise of the international IPR regime has not been fulfilled. Firstly, as noted above, the actual relationship between patents and innovation in developing economies is unclear and secondly, as described in Chapter 2, the international patent system emerged from developed free enterprise economies with a corresponding substantial infrastructure, components lacking in most developing countries.

In the developed world, conventional wisdom holds that the incentive to invent is the legally enforced temporary monopoly with its promised revenue as a means to recoup

295 Park & Ginarte 1997, p. 60.

296 PhD study by Adams (undated), pp. 14-17.

297 Adams (undated), p. 14.

investment (and, hopefully, contribute to shareholder profit), or the moral (as legal theory in continental Europe suggests) and economic reward for creative efforts. Evidence is emerging that incentive to invent is linked to more than the expected monopoly profit only.[298] Other competition motives are at play as well. First, there is a need to stay ahead of competitors and not be pushed out of the market.[299] Second, the dynamics of competition contribute to a drive for new technologies and products.[300] Of course, the nature of innovation is not quite as simple as suggested. Not only is the incentive effect of patents different in various industry and technology sectors but inventions are usually the result of "cumulative incremental improvements" – not "heroic" activity of "rare geniuses."[301] On occasion, obtaining a patent is merely a "windfall gain" for the company or institution in question and not part of a deliberate R&D policy.[302] And of course other mechanisms of protection, such as "trade secrets," exist to protect a business' "internal sphere" from prying eyes and against unfair competition.[303]

In any case, the patent system has become a valuable tool for the inventor to maximize profits – or to minimize losses – either because of the products it protects or because the patent portfolio has become a commodity itself.[304]

### 4.4.5 Myth: "Presence of IPRs guarantee that innovation will happen"

As detailed above in Chapter 3, TRIPS was "sold" to developing countries under the premise that more patenting leads to innovation which in turn creates economic growth. In reality, stronger patent protection in developing countries is, at least in the short term, more to the advantage of outsiders who are generally responsible for the majority of filings. This has the effect of limiting opportunities for locals to either copy, imitate and ultimately innovate. As noted above in Chapter 3, developed countries went through a period of limited intellectual property protection during which time copying and imitation were crucial to the process of developing technological capacity and capabilities.[305] Moreover, comparative analysis indicates that patents do not appear to be a strong motivator of invention and innovation in developing countries, save for economies that are close to becoming developed.[306] Thus, the

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298 Pretnar 2009, countering the traditional view that the incentive to invent is to be found in the expected monopoly profit. Based on his analysis Pretnar argues that there is in fact a dual incentive to invent: not just maximizing profits by being ahead of others, but minimizing losses by staying in the game.

299 Pretnar 2009, pp. 850-851.

300 Examples include the industries for software development – "open source" – and semi-conductors where IPRs have played a marginal role as an incentive for innovation. See Correa 2007, pp. 6-7, with reference to the study by Levin *et. al* 1987 which found that, by that time, many businesses used other means than patenting for securing competitive advantage for new products.

301 Gollin 2008, p. 14, with reference to J. Diamond.

302 Correa 2007, p. 6 and p. 30, note 24.

303 See for a short description of trade secrets and the justification of their protection: Ohly 2009, pp. 546-547

304 With reference to Pretnar 2009, p. 851.

305 See Chapter 3 on history of developed countries.

306 Odagiri *et. al* (eds.) 2010, pp. 427-428. Innovations to modify or improve imported technologies possibly excluded (at p. 428).

mere presence of IPRs does not guarantee that *domestic* innovation will happen, even though that is what developing countries may have been led to believe.[307]

It is not certain whether the reverse is true – does the absence of IPR impede innovation? Currently, African markets are generally dominated by small businesses and a limited range of goods consisting mostly of raw materials such as bananas and crude oil.[308] If the history of Europe, the US and modern India and China are considered, it would appear that once domestic industry and technology have reached a critical level worth protecting, the interest in strong domestic IPRs will emerge.

While developing countries could opt *not* to make patents a central part of their push for innovation until a later date, they do not have a choice under TRIPS (apart from later dates for compliance by least-developed countries). Because of the international requirements for harmonized IPRs developing countries can only create innovation policies within the context of the IPR system.

### 4.5 Incorporating TRIPS Flexibilities into National Standards: Some Remarks on "Access"

Important to achieving MDGs 1 and 6 (health and food security), is the question of *access*. Principle features of "access" are (a) low cost and (b) availability. "Availability" in the case of public health means pharmaceuticals that are either manufactured locally or imported, then transported and kept refrigerated, distributed to medical centres throughout the country, and eventually administered and supervised by qualified medical staff. In the case of seeds, "availability" requires an infrastructure comprising, at minimum, manufacturing facilities, storehouses, and distribution channels. Pharmaceuticals are rarely invented in African countries, and only occasionally manufactured there. The same is true of genetically modified seeds. As a result, countries with severe health and food security problems have to rely on other countries for their supply of medicines and seeds, for which patent protection is often claimed.

Regarding access at low cost, African countries in theory have some options. A government could simply request reduced prices for the products bought directly from the pharmaceutical companies (which may be located in the United States or the European Union, or, in the case of many generics, India). This is unlikely to be an acceptable option for the companies in question. Another approach would be to request the patent owner to issue a "voluntary license" that would permit a local company (perhaps a subsidiary of the multinational) to manufacture the product domestically in the developing country (assuming of course a sufficient local manufacturing capability – an issue of infrastructure). A third option is to seek to benefit from international "patent pools" such as the recently launched "Medicines Patent Pool" supported by Unitaid, which aims to increase access to medicines for people living with HIV in developing countries through voluntary licensing of intellectual property "while giving pharmaceutical companies fair compensation".[309]

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307 See Castle 2011 providing much detail on issues at the crossroads of innovation and IPRs (in the field of biotechnology).

308 Banji & Padmashree 2010.

309 See <http://www.medicinespatentpool.org/> (accessed on 1 July 2011). See also Van Overwalle 2010 on differential pricing and recommendations regarding alternative methods of IP protection, *e.g.* patent pools.

Another potentially useful option available to developing countries would be increased utilization of the *flexibilities* of the international IPR system, specifically the compulsory licensing option of Article 31 of TRIPS.[310] (Introduced in Chapter 3, para. 3.6; see also Box I-17)

In practice, however, there is a long history of pressure on developing countries to not utilize the legal option of compulsory licensing.[311]

Advantages of Article 31 TRIPS are that it can be considered applicable to fields other than pharmaceuticals, including agriculture. Moreover, the grounds on which a compulsory license can be awarded under the provision are essentially left to the discretion of the issuing country and differ considerably between countries.[312] Further, the separate WTO declaration on TRIPS and public health provides extra flexibility to countries unable to produce pharmaceuticals domestically and has the unofficial status of "temporary waiver" although not yet incorporated in the TRIPS Agreement itself (see Box I-21).[313] Politically tainted-disputes influence what is (not) happening on compulsory licensing – "[G]lobal innovator companies are jittery over the use of this provision since it breaks their monopoly and pricing power while local drug makers and health activists are pushing for liberal use of this provision, saying that innovator companies charge an exorbitantly high price for their medicines."[314]

The precise limits of this legal option have not yet been clarified. Only a few developing countries including Rwanda, Zambia and Ghana have taken steps to issue compulsory licenses, for public health purposes, while sometimes the threat proved enough to secure reductions in prices and at other times foreign pressure or drug donations changed a developing country's position.[315] (See Box I-20).

**Box I-20: *Natco Pharma Case India (2011)***

*An interesting case will be Natco Pharma possibly seeking compulsory licence in India from a brand name pharmaceutical company, Bayer AG, for a cancer drug.316 Natco Pharma, a producer of low-cost medicines, plans to seek a compulsory license from the government to make Bayer AG's brand drug Nexavar in India, invoking a provision in local laws that allows generic manufacturers to make and sell patented drugs cheaply if the medicine is unaffordable.*

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310 Discussed in Chapter 3. See, among others, Chamas, Prickril & Sarnoff 2011, pp. 71-76; Avafia, Berger & Hartzenberg 2009, pp. 200-201.

311 Discussed in Chapter 3, para. 3.6. See also Muzaka 2011, p. 36, and generally, including cases, Deere 2009, pp. 82-83 and pp. 229-232.

312 Thorpe 2002, p. 22: "Note should however be made of Article 5 of the Paris Convention incorporated into TRIPS by reference which could suggest that such grounds should relate to the prevention of abuses of patent rights."

313 There is controversy as to whether African countries that lack manufacturing capability are free to order, for example from India, "generic" versions of medicines that are patented in their country. See for an introduction on generics and the price of medicines, Chamas, Prickril & Sarnoff 2011, box 2.1 by C. Trezza, pp. 67-68. See on seizures of generics in the EU, Chapter 5, para. 5.2.4.

314 *The Economic Times* 24 January 2011, <http://articles.economictimes.indiatimes.com/2011-01-24/news/28433936_1_compulsory-licence-natco-pharma-patent-owner> (accessed on 25 January 2011) .

315 Deere 2009, pp. 82-83 and pp. 229-232. Also, Chapter 3, para. 3.6.

316 Reporting in *The Economic Times* 24 January 2011, available at <http://articles.economictimes.indiatimes.com/2011-01-24/news/28433936_1_compulsory-licence-natco-pharma-patent-owner> (accessed on 25 January 2011) .

*"The development, a test case for such licensing in India, is being watched by local and global innovator companies as it could be the first instance where a foreign drug maker would be forced to grant a licence."317 The Indian government can allow generic manufacturers to legally make and sell low-cost versions of patented drugs under certain conditions such as if the medicine is unaffordable for patients by paying royalty to the patent owner. This is controversial as goes against the interests of the patent holder (the 'brand name' pharmaceutical company investing in new medicines) who, in principle, enjoys 20-year exclusive marketing rights to make and sell his medicines in the country.*

While the introduction of a modern IPR system and associated infrastructure is important for a country, it may have adverse effects. In Africa, the sharing of seed among farmers is a deeply rooted tradition that had always been the norm until the introduction of genetically modified seeds on African markets. These "high-tech" seeds, of which there is a growing demand in Africa because of their very useful properties, are generally "invented", produced and supplied by multinational corporations in Europe and the United States that demand local IPR protection and enforcement for their products. The requirement for protection has significantly impacted the local tradition of sharing seed.[318]

**Box I-21*: Importing Cheaper "Generics" Under Compulsory Licensing*[319]**

*THE DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH*
*As indicated in Chapter 3, TRIPS fails to define certain critical terms. One consequence is that it was unclear how the criteria of TRIPS flexibilities could be interpreted or to what extent they could be used. The African Group (consisting of all the African members of the WTO) was among the members pushing for clarification. A large part of this was settled at the Doha Ministerial Conference in November 2001. In the main Doha Ministerial Declaration of 14 November 2001, WTO member governments stressed that it is important to implement and interpret TRIPS in a way that supports public health – by promoting both access to existing medicines and the creation of new medicines. They therefore adopted a separate declaration on TRIPS and Public Health. They agreed that TRIPS should not prevent members from taking measures to protect public health. They underscored countries' ability to use the flexibilities that are built into TRIPS, including compulsory licensing and parallel importing. And they agreed to extend exemptions on pharmaceutical patent protection for least-developed countries until 2016. On one remaining question, they assigned further work to the TRIPS Council — to determine how to provide extra flexibility, so that countries unable to produce pharmaceuticals domestically can obtain supplies of copies of patented drugs from other countries. (This is sometimes called the "Paragraph 6" issue, because it comes under that paragraph in the Doha Declaration on TRIPS and public health.)*

317 *Idem.*

318 See in PART II the case study on agriculture for more details on this topic

319 Excerpted from *WTO Fact Sheet* 2006. Because of its accessible style, this source is useful here, even though it "is not an official interpretation of the WTO agreements or members' positions".

*IMPORTING UNDER COMPULSORY LICENSING ('PAR.6')*

*Article 31(f) TRIPS requires products made under compulsory licensing must be "predominantly for the supply of the domestic market". Clearly this best applies to countries that can manufacture drugs to supply their own market but does limit the amount they can export when the drug is made under compulsory license. It is less useful to countries lacking the ability to make medicines and therefore needing to import them (whether patented or generic) as manufacturing states would technically not be able to produce sufficient for another country's use if limited to amounts for their own market. The legal exporting/importing problem was resolved on 30 August 2003 when WTO members agreed on legal changes to make it easier for countries to import cheaper generics made under compulsory licensing if they are unable to manufacture the medicines themselves. When members agreed on the decision, the General Council chairperson also read out a statement setting out members' shared understandings on how the decision would be interpreted and implemented. This was designed to assure governments that the decision will not be abused.*

*The decision actually contains three waivers:*

- *Exporting countries' obligations under Article 31(f) are waived — any member country can export generic pharmaceutical products made under compulsory licenses to meet the needs of importing countries.*
- *Importing countries' obligations on remuneration to the patent holder under compulsory licensing are waived to avoid double payment. Remuneration is only required on the export side.*
- *Exporting constraints are waived for developing and least-developed countries so that they can export within a regional trade agreement, when at least half of the members were categorized as least-developed countries at the time of the decision. That way, developing countries can make use of economies of scale.*

*Carefully negotiated conditions apply to pharmaceutical products imported under the system. These conditions aim to ensure that beneficiary countries can import the generics without undermining the patent system, something particularly important for developed countries. They include, for example, measures to prevent the medicines from being diverted to the wrong markets and the requirement that governments using the system keep all other members informed although actual WTO approval is not required. At the same time, phrases such as "reasonable measures within their means" and "proportionate to their administrative capacities" are included to prevent the conditions becoming burdensome and impractical for the importing countries.*

*The 2003 waivers are interim; the ultimate goal is to amend TRIPS itself, and a decision to do this was reached in December 2005, accompanied again by a chairperson's statement. The amendment – a direct translation of the waivers – enters into force when two-thirds of members accept it. (This has not yet happened.)*

## 4.6 Technology Transfer

### 4.6.1 Opportunities for Learning, Industrial Development and Growth

Typically, IPRs are an important component of the mechanisms that regulate "knowledge transfer" and "technology transfer" from universities and corporations in the most advanced countries to developing countries. These mechanisms include not only the transfer of IPR-controlled information but also the knowledge of how to use and maintain the technology, under the conditions of license.[320] Developing countries have an evident interest in obtaining access to foreign knowledge and technology that they can then adapt to their local conditions,[321] creating possible opportunities for learning, industrial development and growth.

Technology transfer, "North" to "South," requires an "innovation infrastructure" in both developing African countries and in developed countries.[322] Before developing countries can take advantage of the opportunities likely to result from technology transfer, an appropriate infrastructure must be in place, ranging from industry sectors, universities and government institutions to skilled human resources. "Any economy's ability to produce commercial innovations" depends on a functioning "national innovation system" in which sectors of industry, universities, and the government interact for the purpose of producing innovations and generating growth.[323] In addition, various aspects of infrastructure that have no direct relationship with intellectual property such as government controls on exchange rates, taxes and contractual practices are likely to have a significant impact on the willingness of developed countries to transfer technology.[324]

### 4.6.2 Struggle of Developed Countries with Obligation in Article 66.2 TRIPS

Technology transfer from "North" to "South" is a factor in generating innovation and economic growth in developing countries. As invention and creation processes "overwhelmingly" remain the province of industrialized countries, most developing countries must rely largely on imported technologies as sources of new productive knowledge.[325] Having said this, "considerable amounts of follow-on innovation and adaptation" occur in developing countries and effectively function as driver of technological change in developing countries.[326] This is a major part of the process of developing local capacity.

Technology transfer to developing countries is suggested by Article 66.2 TRIPS, which is primarily addressed to industrialized WTO states. The article provides that "developed country members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base." This

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320 Foray 2009, p. 4.

321 *Idem.*

322 This shows the flexibility of the concept of infrastructure. See on innovation and infrastructure Banji & Padmashree 2010, pp. 7-10.

323 Greenhalgh & Rogers 2010, p. 87, quoting A. Goto (2000).

324 de Carvalho 2005, p. 129.

325 Hoekman *et. al* 2004, p. 1.

326 *Idem*, with reference to R.E. Evenson & L. Westphal, 'Technological Change and Technology Strategy,' in H. Chenery & T.N. Srinivasan (eds.), *Handbook of Development Economics: Vol. 3*, Amsterdam: Elsevier 1995.

obligation can take many organizational forms, such as the establishment of public-private partnerships aimed at transfer of particular technology to African countries. It may also involve different IPR models including licensing IPR-protected matter to users in the developing country.

Despite its apparent potential, in reality Article 66.2 TRIPS has been a disappointment. The ultimate aim of technology transfer – contributing to significant economic growth in least-developed or undeveloped countries – will obviously not be achieved overnight as each developing country is different and a single blueprint for successful partnerships that benefit developing countries is not available. As a 2009 study into technology transfer between developed and developing countries shows, technology transfer is a difficult and complex process.[327] This is particularly true for least-developed countries, which have trouble attracting foreign direct investment and foreign technologies. As poor states with little trade, they have limited "absorptive capacity" for foreign technologies.[328] This means that it is unlikely that even the few foreign technologies that are transferred will find their way throughout the economy.[329] This problem will not be solved just by licensing technology on favorable terms.

The flow of technology transfer, a different study has concluded, depends on many factors such as the proximity to markets, size, growth, competition conditions, human capital, governance, and infrastructure.[330] Many of these variables are affected by policy. While licensing is an important source of technical transformation, it was argued, successful transfer generally requires the capacity to learn as well as the ability of local firms to apply technologies.[331] "Poor countries are most likely to achieve these gains by taking advantage of mature technologies that are in the public domain or available cheaply. Thus policy could aim at improving information flows for domestic enterprises about such technologies."[332] While as a secondary priority in low-income nations, programs could be introduced to build skills and R&D capacity, it has been stressed that broader policy initiatives are necessary if local economies want to gain productivity from technology transfer.[333]

Several other factors could be noted. "Industries differ significantly in where the sophisticated parts of the technologies that must be mastered for effective catching up reside, and also in the extent to which these are protected by patents."[334] In pharmaceuticals, "product design largely involves a chemical compound, which generally is covered by a patent," while in other sectors, in contrast, competitive products such as electronics may require many (patented) components and "engineering design".[335] Understanding these differences is of importance to those who view technology transfer as instrumental to innovation in developing economies.

To make the implementation of Article 66.2 TRIPS – technology transfer from developed to developing countries – more effective it is being suggested that developed

327 Foray 2009, p. 56.

328 Foray 2009, p. 56.

329 R. Mélendez-Ortiz in: Foray 2009, p. vii (foreword).

330 Hoekman *et. al* 2004, p. 28.

331 *Idem.*

332 *Idem.*

333 Hoekman *et. al* 2004, pp. 28-29.

334 Odagiri *et al*. (eds.) 2010, p. 421.

335 Odagiri *et al*. (eds.) 2010, p. 421.

countries should offer assistance to projects that are "socially beneficial but not profitable for the firms that own and could transfer the technology".[336] This has the virtue of being a possible alternative incentive for private sector parties in the "North" to become engaged in technology transfer, but does not answer the question how developing countries should become involved and who will organize such an operation. It is therefore suggested that initiatives for technology transfer should be based on local demand for technology and with the involvement of relevant partners – particularly, in case of public-private partnerships, a third party "which is specialized in linking public donors, private firms and local entrepreneurial activities".[337]

More issues remain to be solved. The aim of promoting technology transfer e.g., between (public) universities in the "North" and the "South" is impacted by questions over existing IPRs and future uses. The knowledge, materials and technology involved in such transfers are usually subject to intellectual property rights. This impacts universities in the "North", for example, who are concerned about not being held responsible for anything that they share because of IPR-related issues e.g., protected data and copyrights. Questions to be considered are how to obtain permission for protected technology such as this to be transferred in the first place and, once transferred, what would be the scope of its use for "development purposes".[338] A related, but also more general issue is that technology transfer programs of industrialized countries tend to emphasize the enforcement of the IPRs of their companies, rather than putting development goals first.[339]

The relationship between universities and private companies is complex. Private companies may be prepared to provide funding for research purposes on the condition that they profit from any products and further that they will own, or at least control, any intellectual property that will arise from the research. Some recent initiatives such as Medicines Patent Pools (http://www.medicinespatentpool.org/) may work differently, in the sense that participating pharmaceutical companies provide IPR-protected knowledge, technology and materials (under certain conditions) with their benefit not being control but something else.

In addition to technology transfer from the "North" to the "South", for example between public universities, opportunities for "South-South" partnerships could be explored. An obvious way of initiating such partnerships is by expanding and intensifying regional cooperation. Moreover, it could be considered what – more proactive – role the "South" may be able to play in guiding and influencing technology-transfer activity in the "North" more effectively.

### 4.6.3 Understanding Patents

As mentioned above in Chapter 3, para. 2.2, with regard to patents, the grant of temporary exclusivity is accompanied by the duty of the patent holder to disclose the invention. Article 29 of TRIPS, requiring that "an applicant for a patent shall disclose the invention in a manner

336 Foray 2009, p. 56.

337 *Idem.*

338 This issue, including the "humanitarian use license", will not be pursued here. On the subject of patents in a university environment, see Van Overwalle 2006a and 2006b.

339 Chamas, Prickril & Sarnoff 2011, p. 81, with references and pointing to discussion elsewhere in Wong & Dutfield (eds.) 2011.

sufficiently clear and complete for the invention to be carried out by a person skilled in the art", taken in conjunction with Article 12 of the Paris Convention which requires regular publication of "a brief designation of the inventions patented" ensures that the public has access to the knowledge of the invention. The internet has made available millions of patent documents around the world via the various major national or regional patent offices.

The transfer of technology from developed to developing countries is an issue covered in Article 7 TRIPS, which speaks of "the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare." However, there are two issues of significance in this regard. First, those reading the relevant patents must be sufficiently technologically sophisticated to be able to understand the specifications and claims. Second, patents are "legal" documents, not "scientific" documents. Their role is to define the limits of an invention – like a "land-deed" defines real property borders. Cynics might suggest that the "art" of drafting patents "so that they disclose as little information as possible - while broadening the scope of the claim as widely as possible" further hampers their use as a source of information.[340] Additionally, what might be considered as basic knowledge to a scientist in a developed country, and therefore appropriately excluded from a patent specification, may not be similarly available to a reader in a developing nation.

The gap between a patent document and fully understanding the invention it describes may significantly compromise the patent as a source of information and technical knowledge.[341] To tap into the knowledge contained within patents requires that the citizens of developing countries such as scientists not only have the necessary scientific background but are aware of the knowledge contained in patent databases and have the infrastructure – e.g., computer and internet access – to access them.[342]

## 4.7 Patent Offices

### 4.7.1 Quality of Patent Administration

In addition to passing the necessary legislation, in order to have a successful domestic intellectual property system a country must create the necessary administrative infrastructure.[343] The administration of national and international intellectual property (patents, trademarks, etc.) requires not only a designated patent office but also the contribution of other governmental groups particularly in the area of enforcement.[344] What is most appropriate for a

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340 de Carvalho 2005, p. 130, footnote 359, referencing Brenner v. Mansion, 383 U.S. 519 (1966) pp. 533-534.

341 See on the importance of this feature of a patent system for learning, Gervais 2007b, p. 545.

342 Other issues are raised by Drahos 2010, p. 318 ff. "It is not immediately obvious, for example, that a developing country which imports medicines should follow the pharmaceutical examination standards of developed-country patent offices that are prepared to accept the gaming behavior of patent attorneys in the drafting of patent claims" (Drahos 2010, p. 318).

343 Problems resulting from a lack of appropriate infrastructure are discussed above.

344 For example, the US Patent and Trademark Office (USPTO), admittedly one of the largest in the world, employs 2,500 examiners who in 2010 examined a total of 520,277 patent applications (comprising utility, design and plant patent applications). Most of the routine business conducted with the USPTO can be done electronically – see, < http://www.uspto.gov/ >(accessed on 1 July 2011) . The European Patent Office employs 1,900 examiners who examine over 78,000 applications per year (1995 statistics).

country that decides to introduce, or upgrade, its patent office to be compliant with the needs of the modern IPR system?[345]

First, in order to be granted, a patent must be shown to have "novelty" and an "inventive step" (European patent law) or "non-obviousness" (in the United States) in relation to existing scientific and technical knowledge. Evaluating these criteria, the process of patent examination, is one essential function of a country's patent office. A poorly examined patent is likely to be successfully challenged by competitors and therefore hardly worth the application and examination fees, much less the amount spent on commercializing it.

Second, in some developing countries patents are not even examined but merely registered. In South Africa, for example, the "formal examination" of a patent consists of ensuring that "all the formalities have been complied with" and once that is completed "the application is accepted."[346] In other African states, patent offices have great difficulty performing their task because patent examiners there usually lack the tools to effectively access, and the knowledge to evaluate, the scientific and technical knowledge comprising the relevant "prior art." In addition, if a patent office develops a backlog of unexamined patent applications, it will breed uncertainty.[347] In short, a country with a poorly developed or organized patent granting system will discourage foreigners from using the system (although of course if there is a market for their product in the country they will likely prefer to obtain whatever patent protection is available). In other cases, some file in countries like South Africa despite the fact that it has a non-examining patent office, as they know that it will lead to an easy patent grant.

Finally, a well-organized patent office capable of proper application examination must recruit, train and maintain a strong cadre of examiners – a task beyond the financial and educational means of many developing states. Arguably, developing countries do not require the range of expertise needed to staff a patent office in an industrialized country.

Regardless, whether a developing country hopes to attract sophisticated foreign technology or requires access to the latest HIV treatment, it must have a patent infrastructure, including a competent patent office, to make its grant of a patent meaningful. This includes not only the personnel but also ready and inexpensive access to electronic databases and rapid search engines. A strong patent system provides reassurance to foreign inventors including the powerful multinational companies and potential investors that their inventions are unlikely to be pirated (the original motivation behind TRIPS). This is the principal motivation for developing countries with limited technological capability and human resources, such as most countries in the Sub-Sahara region, as there is no local use for a strong IPR system.[348]

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345 Extensively on patent offices and their duties, Drahos 2010, among others pp. 33-38.

346 In this system, the "strength" of a patent is determined by the attorneys who file it and competitors who challenge it via an infringement proceeding. See, Companies and Intellectual Property Registration Office ("CIPRO") <http://www.cipro.co.za/products_services/patents_registration.asp> (accessed on 1 July 2011).

347 Then-European Patent Organization president A. Brimelow is reported to have stated in 2009 that better and fewer applications are needed including better prior art searches; <http://ictsd.org/i/news/bridgesweekly/55777/> (accessed on 1 July 2011) .

348 Compare Odagiri *et. al* (ed.) 2010, pp. 420, 424 and 428.

### 4.7.2 The Cost of Patenting

The cost of "patenting" is high. Not only are there the costs of setting up the administrative aspects - patent offices, training of personnel, training of judges, lawyers - but also the actual costs of the process to the patent applicant - attorney fees including searching for prior art, preparation of application, filing. Related to this, patent administration in developing countries is often targeted at obtaining fees from foreign applicants (multinational corporations), but for local applicants a $100 fee may represent several months' salary - indicating that it is problematic to simply view IPRs as tools for economic growth. Moreover, in the case of possible infringement, litigation is expensive. All of this means that running a viable patent system, and participating in it, is expensive and is therefore a limitation for poorer countries having other priorities. Further, obtaining patents in the major markets (the US, the EU, or Japan, for example) is expensive.

## 4.8 Regional Cooperation in Sub-Saharan Africa

> "With a very large number of small economies, 15 landlocked countries and 63 shared river basins, Africa's infrastructure needs have to be addressed in a regional manner if countries are to reap the benefits of economies of scale, develop intra-African trade and enhance competitiveness in the global economy. Therefore, increased financing is required for regional power pools, transport networks, backbone communication infrastructure, and trans-boundary water management."[349]

This approach is especially relevant to Sub-Saharan Africa where improving basic infrastructures could be done in groups of countries located in the same area at the same time.

Countries that want to set up an IPR infrastructure, within the framework of an innovation system (para. 4.3), could also benefit from regional cooperation with their neighbors. Increasing such "South-South" cooperation is worth considering and could be extremely valuable for such tasks as shared patent searching and examination. Developing countries could also consider the potential benefits of a regional system of intellectual property rights – one that fits with local demands and circumstances. A downside of regional IPR systems in developing countries would be that the major developed nations are unlikely follow its rules if it is not to their benefit – i.e., there has to be a system that benefits both domestic and international needs although the current international system is not considered by developing countries to benefit the "South".

A sign of the "South" gaining more "clout" may be that the importance of regional trade integration in Africa is growing, implying that developing countries are actively engaged in regional cooperation. This cooperation leads to regional trade agreements that are best understood as "flexible legal regimes" given their commitment to multiple memberships, among others.[350]

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[349] MDG Africa Steering Group 2008, pp. 16-17.

[350] As argued by Gathii 2011 (forthcoming) based on analysis of the legal framework of African regional trade integration.

### 4.9 Multitude of international development actors

One problem affecting both the implementation of TRIPS and infrastructure in developing countries is that it is hard to keep up with the multilateral system.[351] The many different agencies in the international arena bring different approaches and dynamics and are viewed by some as "unwieldy" in global negotiations and norm-setting.[352] The lack of coherence between agencies and regimes in IPR-related areas has produced a virtual "legal swamp" with overlapping interests in the areas of competency, definition and scope.[353] For example, the biodiversity regime system includes often competing initiatives in the respective areas of agriculture, trade, biodiversity and intellectual property. In health, too, many agencies are involved, with many international development initiatives.[354]

In fact, as the EU has reported, progress has been undermined by an "unbalanced and fragmented attention to health priorities" with "more than 140 global health initiatives targeting specific needs often run(ning) in parallel and … adding pressure on already weak health systems."[355] The abundance of agencies and the lack of streamlining of initiatives have complicated the introduction and management of IPR regimes in the developing world. There is a continuous need for coherence of donor policies (see Chapter 1, para. 2.1.11).

### 4.10 Enforcement

#### 4.10.1 IPR Enforcement Priority of Developing Countries (mostly multinationals)

An essential component of IPR infrastructure is "enforcement" (see above, Chapters 1, para. 1.2.8 and 3). Adequate IPR legislation, usually a technically complex area, is meaningless unless a country has an effective enforcement system.[356] Legal systems must be sophisticated enough to not only enforce legal rights – judging infringement, invalidity et cetera – but also ensure the competency of the patent granting system. From the international perspective, "tightened measures against IPRs violations are in the primary interest of right holders in developed countries, who control the vast majority of IP-protected intellectual assets worldwide."[357] IPR enforcement is a priority for developed countries but a burden to developing countries, which often do not have the mechanisms in place to provide the necessary enforcement.[358]

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351 Matthews 2011 describes and analyses the (substantial) role of non-governmental organizations in facilitating developing country' governments. See also Deere 2009, p. 197 ff on government capacity on IPR-decision making: relevant factors are the depth of government expertise on IPR issues, the administrative competence of government institutions, and the ability to maintain control of national IPR offices (p. 197).

352 C. Saez, 'Coherence needed to avoid multilateral legal swamp, WTO told', *IP Watch* 22 September 2010, reporting on <www.ip-watch.org> (accessed on 1 July 2011) .

353 *Idem.*

354 Reference is made here to international development policy, Chapter 1, para. 2.1.11.

355 *EU Global Health* 2010, p. 3.

356 See for a detailed introduction into enforcement in a developing country' context, Fink 2009a; Correa 2009.

357 Correa 2009, p. 59.

358 Urbas 2005, pp. 320-321 concludes that public enforcement of IPRs can be highly effective "if sufficient priority, resources an expertise are directed to the problem" including an "active role by customs, police and prosecution authorities."

Rights holders in the private sector in the "North" are particularly concerned about adequate enforcement in developing countries. In the years following TRIPS there has been a campaign by developed countries to improve IPR enforcement, with the Group of Eight developed countries (G8) and others exploring new standards.[359] The main source of concern, and therefore pressure, can be traced to European, Japanese and United States-owned multinationals seeking to increase the value of their exports and expand their global market revenues (see also Chapters 3 and 5).[360]

A telling example of this campaign is the now-halted SECURE-program on IPR-related border measures that was launched by the World Customs Organization (WCO) in 2008 following the July 2005 G8 Summit.[361] This program aimed at creating extensive measures for national customs authorities to combat counterfeiting and piracy worldwide. SECURE proposed standards meant a significant departure from TRIPS provisions in terms of subjects, scope and measures of protection and member states' obligations and rights.[362] The WCO was also a surprising forum for IPR issues, apparently a result of forum-shifting following the "sticky situation" in traditional forums with regard to IPR enforcement initiatives[363] – the issue of "forum shopping" is quite common in the IPR enforcement arena. Critics were concerned that the position of the developing world was given insufficient thought and feared that the "voluntary" rules would be made compulsory soon by way of treaty.[364] Through coordinated efforts developing countries managed to succeed in their strategy to question WCO's approach that was widely regarded as being both exclusive and TRIPS-Plus.[365]

The change in forums for IPR enforcement seems to be a more general issue, especially for those countries that operate outside the 'inner circle' of states that advocate IPR protection and enforcement internationally. A prominent example in the international IPR debate on developing countries is the involvement of WTO (TRIPS) and WIPO (Development Agenda). These two international organizations have seen their mandate on IPR matters changed more than once, political instruments as they are in the negotiations between member states.[366] This is also an issue of influential countries introducing issues in whichever forum seems likeliest to achieve their preferred outcome. Besides changes in (and competition over) mandate, organizations themselves have become involved in a broad range of subject matters outside their core activity. They want to be well-informed and they want to expand. Following the SECURE debacle, the WCO Enforcement Committee signaled that it would now engage in health issues. This raised questions as to the role and mandate of this essentially customs organization.[367] Another example, the World Health Organization (WHO) announced in May 2010 its engagement in the International Medical Product Anti-

359 Correa & Li 2009, p. xix-xx, Tellez 2009, p. 5.

360 As described by Tellez 2009, p. 5, with reference to Correa 2000, p. 4.

361 Li 2009, p. 64.

362 Li 2009, p. 68, with comparisons of SECURE and TRIPS provisions on pp. 69-71.

363 Li 2009, p. 62.

364 Li 2009, p. 74.

365 See in more detail Li 2008.

366 See for example Tellez 2009, pp. 5-7 on forum-shifting from WIPO to WTO.

367 W. New, 'WCO kills 'SECURE' group, but creates health enforcement mandate', *IP Watch* 9 July 2009, reporting on <www.ip-watch.org>(accessed on 1 July 2011) .

Counterfeit Taskforce (IMPACT).[368] As a means of monitoring and influencing IPR enforcement developments this engagement of organizations makes sense, although the picture gets complicated.

Finally, the growing number of commitments has become a concern. "The ability of developing countries, including least developed countries, to integrate development concerns into their intellectual property systems is constrained by the growing number of multilateral, regional and bilateral commitments they continue to make in the area of intellectual property."[369] And: developing countries adopting TRIPS-plus standards for the enforcement of IPRs "further hinder their ability to tailor their intellectual property systems in accordance with their national development priorities."[370]

### 4.10.2 Enforcement Push: Counterfeiting and Piracy

One of the main drivers of "TRIPS-Plus" enforcement rules, it appears, is the need to combat acts of counterfeiting and piracy in developed and developing countries. The merits of curbing counterfeiting and piracy are generally obvious although, as a careful review of their history reveals, today's developed countries preferred to design their IPR laws in a way that suited their economic interests at the time (including having IPR laws that discriminated against foreigners while protecting locals).[371]

Currently, significant confusion exists about the types of acts of counterfeiting and piracy the laws cover. For example, a 2009 study has found that "[A]lthough trademark counterfeiting and copyright piracy are very specific types of infringement, there seems to be an attempt to extend the rules applicable to them (particularly, criminal sanctions and ex-officio intervention) to other forms of IPRs infringements."[372] As that study argues, such attempts by countries with large domestic industries ignore the nature of various IPRs and the modalities that infringement may assume.[373] Criminalizing patent infringement, currently a "civil" matter in most jurisdictions, is one approach on the "wish-list" of industries in developed countries. These industries permit misconceptions about IPRs to continue for example by fostering the belief, common in developing countries, that once a product is patented in the US or EU, it is protected throughout the world.[374]

There are reasons to be critical of this trend, especially when fears over competition mix with other, public interest concerns that in fact do require close monitoring by authorities. Extending the rules to combat acts of counterfeiting and piracy runs the risk of over-protection and abuse, notably in the case of patents, the validity of which may not be automatically presumed.[375] Interferences with the private sector are regarded undesirable, and must therefore be exceptional and specific to a defined situation. On the other hand, authorities are right to lend particular consideration to those acts of counterfeiting and piracy

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368 'NGOs concerned over WHO's role in 'counterfeit' drugs, IMPACT, *Third World Network* 17 May 2010, as published on www.twnside.org.sg (accessed 17 December 2010).

369 Tellez 2009, pp. 3-4.

370 Tellez 2009, p. 13.

371 As has been observed by Drahos 2002, p. 29 ff, among others.

372 Correa 2009, p. 59.

373 *Idem.*

374 Professor J. Kinderlerer, University of Cape Town, personal communication, October 2010.

375 Correa 2009, p. 59.

that could have a detrimental effect on public health – e.g., unregulated (counterfeit) drugs or medical devices. For these serious safety issues, non-IPR approaches, such as criminal law penalties, are an option.

### 4.10.3 Enforcement System Sophisticated and Costly

With respect to the general enforcement obligations, procedures should be available that "permit effective action against any act of infringement" of IPRs.[376] Procedures must be fair, equitable and not unnecessarily complicated, costly or time consuming. The judicial authorities must be granted the power to require infringers to pay damages sufficient to compensate the right holder for the injury suffered due to the infringement. Members are required to provide for criminal procedures and penalties "at least in cases of willful trademark counterfeiting or copyright piracy on a commercial scale".[377]

WTO Members are not required, however, to put in place a separate judicial system for enforcing IPRs. Moreover, TRIPS creates no obligation to shift resources away from general law enforcement towards the enforcement of IPRs. Nonetheless, resource-poor countries continuously face a dilemma when determining how to allocate their scarce resources in this as well as many other areas. The costs must be borne before possible benefits of a stronger and more effective IPR system accrue. Least-developed countries will find it especially hard if not impossible to find the money and the political will.[378]

## 4.11 Relationship to Other Areas: Competition Law

IPRs do not exist in isolation: competition law is a necessary component of an advanced IPR system.[379] From an economic perspective, the role of competition law in the presence of IPRs can generally be seen as "countering the abuse of exclusive rights beyond the purpose that IPRs intend to serve".[380] But while TRIPS 'brought IPRs to Africa', there was no similar drive for accompanying competition systems in African countries.[381] A functioning competition law system has both the laws specifically aimed at regulating market power and the policies and institutions that affect a country's competitive environment.[382] Enforcement is essential here, too.

While IPR law "deliberately subjects intellectual assets to the exclusive control of right owners, competition law seeks to avoid market barriers".[383] Competition law also seeks to benefit consumers by encouraging competition among suppliers of goods, services and

376 ICTSD & UNCTAD 2003, p. 49.

377 *Idem.*

378 *Idem.*

379 See for a detailed introduction into the relationship between the two areas, Correa 2007. See for a comprehensive analysis of current competition law in the EU, the international context of competition law and the influence of EU competition law in international (multilateral, bilateral) agreements, Papadopoulos 2010.

380 Fink 2009b, p. 364.

381 See Cottier 2006, pp. 13-18 on TRIPS and public health, for an illustration of the problems caused by the absence of functioning competition law systems in developing countries.

382 Correa 2007, p. 28, notes 1-2.

383 R. Meléndez-Ortiz, in: Correa 2007, p. vii (foreword).

technologies.[384] But this is difficult to achieve in developing countries with little or no history of competition law and policies. In fact, here, IPRs "have been expanded and strengthened in the absence of an operative body of competition law, in contrast to developed countries where the introduction of higher levels of IP protection has taken place in normative contexts that provide strong defenses against anti-competitive practices."[385]

Developing countries in Africa are in the process of creating competition laws. Current initiatives include, for example, a regional competition law for the regional organization ECOWAS in West Africa, an initiative that has is its origin in Economic Partnership Agreement negotiations with the EU.[386] Most regions have a regional law and a significant number of individual countries have drafted or introduced national laws.[387] This should make them less vulnerable to certain unfair practices in international trade, in particular by multinationals whose influence in the markets was left unchecked.[388]

In its 2008 report on international trade law, the International Law Association identified episodes of price fixing across borders by private companies to the detriment of developing countries. Cartels have been able to manipulate consumer prices in developing countries causing them to increase by 20-40% in affected sectors. Without effective unfair competition policies and laws ("antitrust" in the US legal system), such practices remain unsanctioned and consumers will keep paying too much.[389] This is a case where 'urgent repairs' are needed. "Competition law is one of the indispensable tools in what should be in the kit of any economic reform program."[390] While establishing rules against cartels is important, there are other kinds of abusive dominance associated with IPR ownership, such as restrictive licensing.[391]

Initiatives to enhance competition in African developing countries in the past have tended to focus on fostering possibilities for international trade, and thus also benefit industrialized countries. For instance, reforms were made in developing countries to privatize state-owned enterprises and to open up markets to attract new entrants.[392] However, without a comprehensive competition law system including effective enforcement, maximizing profits at the expense of others will remain a source of problems, in particular for consumers. At the moment, developing African countries possess merely elements of a comprehensive competition law system in various existing laws and policies, while too many agencies have a task and coordination is a problem.[393]

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384 *Idem.*

385 *Idem.*

386 A concern of African countries is that small industries and service providers will not be able to survive free competition from the much larger European companies; stated by L. Ugbajah, Executive Director, Initiative for Trade, Regulatory Reforms and Development (ITRRAD), Abuja, Nigeria, commenting on (and mentioned in) Fundira 2010.

387 See for the influence of the EU on this development, Papadopoulos 2010.

388 Fundira 2010.

389 *ILA* 2008, pp. 740-741, para. 52-54.

390 L. Ugbajah, Executive Director, Initiative for Trade, Regulatory Reforms and Development (ITRRAD), Abuja, Nigeria, commenting on and mentioned in Fundira 2010.

391 Fink 2009b, p. 366.

392 L. Ugbajah, Executive Director, Initiative for Trade, Regulatory Reforms and Development (ITRRAD), Abuja, Nigeria, commenting on and mentioned in Fundira 2010.

393 Fundira 2010.

As mentioned, a number of Sub-Saharan countries are involved in setting up competition legislation, and establishing competition authorities. This process provides an opportunity for countries to ensure that the TRIPS flexibilities are used to maximum effect, i.e., introduced or improved upon and with maximum policy space preserved to make sure the countries has options.[394]

### 4.12 Conclusion

The introduction of a modern IPR system is valueless where there is no solid legal, economic and educational infrastructure, and where it is not included within the context of human development reforms.[395] If infrastructure is lacking or failing, IPRs can and will only benefit stakeholders from already strongly developed countries, a notable imbalance affecting legitimacy in developing countries.

IPRs are no "magic remedy" to solve underdevelopment. IPRs in themselves do not lead to innovation and economic growth. They are in the end and in essence something of a "luxury", be it a useful luxury if the context allows it, furthering economic development where it is already in place.[396] Even similar levels of IPR protection and enforcement can have a differential socio-economic impact, depending on the stage of development and the cultural context.[397] (And if there is no local implementation of domestic IPR legislation, no impact other than the high costs of setting up an IPR system).

For developed countries, with typically a long experience with IPRs, it can be hard to see beyond the benefits to them, resulting in a "Northern" economic and legal-technical view of IPRs. But the developed countries have a responsibility to consider the differential impact of implementing the international IPR framework, considering that they were the driving forces behind the creation of global IPR standards and knowing the difficulties the (much poorer) developing countries experience with acceding to those standards.

To stress the disparity, it is reiterated that countries in Sub-Saharan Africa face difficulty with infrastructure even at the most basic level. Improving transport, food, sanitation, drinking water, trained medical staff and adequate equipment are critical to achieving the MDGs. This provides business opportunities for large foreign corporations bringing specialized knowledge and the money to invest, e.g., developing power and communication networks.[398] Foreign involvement could thus have a substantial role in shaping local infrastructure in Sub-Saharan countries.

The potential to benefit from TRIPS-compliant IPR systems depends to a significant extent on the presence of advanced technology and manufacturing capability, and skilled

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394 Avafia, Berger & Hartzenberg 2009, pp. 200-201.

395 Among others, Wong & Dutfield (eds.) 2011, pp. 1-4; Gervais 2007b, pp. 545-546; Lee 2006, p. 160; Hoekman & Kostecki 2009, p. 565. Siemsem & Ahlert 2009, p. 651 write that, judging by the economic progress of such countries as South Korea, India and Brazil, there are no successful innovation programs if a preliminary educational effort is missing.

396 The term "luxury" is borrowed from Mgbeoji 2007.

397 Wong & Dutfield (eds.) 2011, p. 3, referring to various sources, among which Park & Ginarte 1997.

398 A. Wooldridge, 'The emerging emerging markets. Businesses will learn to look beyond BRICs', *The Economist* 2011, Special Edition *The World in 2011*, pp. 117-118. See also P. Thaker, 'South of the Sahara. Boom time, at least in parts', in same publication, at p. 86.

human resources.[399] In developing countries where this is clearly the case, designing and establishing appropriate infrastructure might make sense from their perspective, involving a range of legislative, executive and judicial government departments. For other developing countries, complying with the international IPR system might make no sense at all, depending their specific stage of development. For least-developed countries, temporary exemption is granted from the obligation to become TRIPS-compliant (see Chapter 3) – which does not solve their development problems but at least gives them a break from the IPR demands that accompany international trade. But it is the remaining large and diverse group of developing countries that struggle to position themselves.[400]

The relationship between patenting and innovation is complex, probably indirect only, and in any case country-specific. For developing countries entering the arena of sophisticated IPR law- and policy-making, expectations with regard to innovation and IPRs have to be clearly understood. Essentially, IPRs, in isolation, have little value if they are not supported by well-informed and well-equipped government agencies, coordinated policy programs, and adequately trained staff, among others. For example, Uganda's Trade and Intellectual Property Program (2008) shows the extensive requirements and high cost of becoming TRIPS-compliant.[401] The efforts may however have positive 'pay-off effects' for other areas of the law and institutions in developing countries, which, if realized, are in fact a contribution to development of the countries concerned.

Enforcement means that rights are actively protected. Here the interests of developing and developed countries diverge, because of different needs and different levels of industrial and overall economic development. While developed countries are interested in more enforcement and have sought various means of achieving this, including demanding additional rules, developing countries are more concerned about the additional burdens involved in complying with these. Developed countries' governments face a dual responsibility – both towards their own industries and towards trading partners, both developed and developing. In the case of Europe, "protection and enforcement of intellectual property are crucial for the EU's ability to compete in the global economy,"[402] while the developing country trade partners hope that EPA-negotiations will result in fair deals that will improve their infrastructures and IPR systems. Sadly, the two narratives cannot always both be true.

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399 As found by Ostergard 2007, pp. 152-155; Odagiri et al. (ed.) 2010, pp. 420, 424 and 428.

400 With regard to setting up IPR systems, developing countries are likely to be motivated most by the (increased) potential for international trade and foreign investment, Ostergard 2007, pp. 153-154.

401 *UTIP* 2008. See background of Uganda's Trade and Intellectual Property Program at <http://www.uncst.go.ug/site/documents/Background%20document%20on%20IP.pdf> (accessed on 1 July 2011).

402 <http://ec.europa.eu/trade/creating-opportunities/trade-topics/intellectual-property/index_en.htm> (accessed on 1 July 2011).

# CHAPTER 5 POWER DIFFERENTIAL

## 5.1 Introduction

This Chapter covers those obstacles related to what could be called the "power differential" between developed and developing countries.[403] A recurring feature of difficulty that developing countries face is that their relationship with industrialized countries is uneven, a consequence of the differential in economic, trading, and negotiating power (see Box I-22). Likewise, the international IPR regime, which was essentially designed by stakeholders in developed countries and adopted worldwide, has also been implicated in this (as was shown in Chapter 3). While the negotiating history of TRIPS reflects a complicated process started decades ago, IPRs are dynamic (Chapters 1 and 2) and balancing their multiple components is an ongoing process. Today, the many theoretical and empirical studies into IPRs being undertaken internationally continuously add to and readjust knowledge and convictions about the functions of IPRs in society, effective IPR systems, cultural perspectives, and the development context of developing countries improving legal (IPR) systems, and influence views on the international IPR system and its implementation. Therefore, while in a sense the product of the power differential between developed and developing countries, TRIPS has not carved the power differential in stone.

Sub-Saharan countries, individually and regionally, lack the substantial infrastructures necessary for coping with the demands of modern international trade, as was detailed in Chapter 4. However, Sub-Saharan countries are at various stages in the process of development. Therefore, the differential between such countries as South Africa – developed in certain ways, developing in others – and Uganda – a least-developed country – is considerable, too. Common concerns with countries in the Sub-Saharan region, such as poverty, public health, education, governance, and the economy, led to a relationship of dependency on foreign aid and loans, which limits choice. Recently, since the MDGs were launched and countries in the region adopted appropriate domestic policies, this dependency seems to be receding, as developing countries have gained some power setting their own agenda.[404] In addition, as for IPR systems, efforts of designing and implementing such systems in developing countries have spillover effects with regard to other areas of the law. While the implementation is generally a burden given the lack of infrastructure, the cost and manpower, development priorities, as discussed in Chapter 4, the experiences and the resulting system will reflect on the overall performance of the country's legal, policy and administrative system. Moreover, as regional partners, Sub-Saharan countries can share experiences and create model laws, as they have already undertaken to do.

**Box I-22:** ***The Power Differential in GATT Negotiations***

*Developed countries, notably the US and EU, entered the GATT negotiations with a definite agenda. "There was an assumption that, unlike WIPO negotiations where countries had to consider only the direct arguments for and against higher standards of protection, the GATT negotiations would force developing countries to offer concessions on IPRs in exchange for*

[403] The idea of the differential in power between developed and developing countries has been described by multiple authors. Compare, for example, Okediji 2009.

[404] Beyond Midpoint 2010, p. 8.

*what they might gain in other fields (e.g. agriculture, textiles, and tropical products). An additional appeal of the GATT forum for the developed countries consisted in the opportunity it provided for effective enforcement of agreements and for dispute settlement mechanisms, both of which were practically lacking in the WIPO-administered conventions."*[405]

*Although initially very resistant, developing countries were persuaded to accept higher IPR standards utilizing the GATT-based approach.*[406] *This was achieved because: (a) the US made effective IP protection a condition for access to the US market for developing countries with promises of lowering tariffs and quotas and reducing agricultural subsidies (the "carrot"); (b) the US and later the EEC (now the EU) threatened trade retaliation if IPR protection in a developing country was not considered sufficient (the "stick"); (c) effective IPR legislation was equated with a good conduct certificate as developing countries adopted free market policies; and (d) developing countries hoped that acceptance of a multilateral framework was preferable to bilateral concessions and might in any case lead to trade-offs in other areas.*[407]

*Not all countries were immediately capable of implementing the TRIPS requirements. Governments had to consider "diverse and complex" concepts that were often unfamiliar particularly to "civil servants, judges and law enforcement officials."*[408] *Additionally, political opposition challenged the approval of certain obligations, a notable example being the protection of micro-organisms and plant varieties as required by Article 27.3(b).*[409] *However, despite these possible limitations, and even though they did not have to do so until 2016, under the auspices of WIPO, ARIPO and OAPI, most African countries have passed the necessary legislation to provide patent protection for pharmaceutical products.*[410] *(The "flexibilities", exceptions to those obligations, are a separate issue, see Chapter 3).*

*Despite the pressure from developed countries, a group of developing states (the "Group of 14"*[411]*) did manage to include a number of objectives and principles considered by them to be especially important. Their proposals for inclusion in the agreement include areas ranging from counterfeit goods to "the standards and principles concerning the availability, scope and use of intellectual property rights."*[412]

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405 Correa & Yusuf (ed.) 2008, p. 9.

406 Note that the US also had to modify its law following institution of the TRIPS Agreement via the "GATT legislation" – the Uruguay Round Agreements Act, 108 Stat. 4809, 4973-4990 (1994). Examples of changes introduced into US patent law included changing the expiration date of US patents to 20 years from the date of application filing, expanded the definition of infringement to include the acts of unauthorized offering for sale and importing and added a new procedure for filing "provisional applications". Reference: Merges 2002, p. 58.

407 Correa & Yusuf (ed.) 2008, p. 9.

408 de Carvalho 2005, p. 67.

409 *Idem.*

410 Among others, Osewe 2008, p. xii.

411 The "group of 14" consisted of Argentina, Brazil, Chile, China, Colombia, Cuba, Egypt, India, Nigeria, Pakistan, Peru, Tanzania, Uruguay and Zimbabwe.

412 Correa & Yusuf (ed.) 2008, p. 9.

## 5.2 "Great Expectations"[413]

### 5.2.1 "North" Expecting Rapid Introduction and Functioning of IPRs

Developed countries "took over two centuries to design, experiment with and progressively institute national intellectual property systems, (while) developing countries for the most part absorbed foreign-imposed intellectual property systems due to colonial rule." [414] Subsequently, "increasing globalization and international trade" changed the international trading landscape yet again and "brought new external pressures on developing countries to (rapidly) reform their intellectual property systems" in the era of TRIPS-plus.[415]

A review of the history of their own IPR regimes establishes that the US, the EU and other industrialized countries ignored their own experience when swiftly setting up IPR systems in developing countries.[416] The expectation of developed countries that developing nations must quickly and efficiently adopt and utilize international IPR standards does not at all accord with their own history.

In addition, it is unclear how much local use for IPRs exists in developing countries. Evidence has been found that companies in low-and middle-income countries often do not patent their inventions because they cannot afford to defend them.[417] Even in those cases where inventors in developing countries do patent their inventions, there may be reluctance to challenge possible infringement by foreign corporations so as not to damage relations with the valued trade partner. This relates to the power differential, in the sense that African countries are often depending on a few export products or commodities only, which leaves them little alternatives. Examples of typical African exports include raw materials such as copper, iron ore and coal destined for large consumer markets mostly in the EU, the US and China.[418]

### 5.2.2 Innovation Protection vs. Unfair Control in Medicine and Seed Sectors

Not surprisingly, multinationals are generally the defenders of "strong" patents. They argue that patents are necessary to protect, and thereby stimulate, innovation. Access by the public to new inventions, it is argued, must be, at least temporarily, controlled in order to permit an inventor to recoup the cost of R&D.[419] A patent system with the grant of exclusive control will ensure that if the invention is commercially successful, the inventor will not only recover his R&D costs but also make a reasonable profit. The same rationale is found in international IPR law and policy. As users rather than producers, developing countries, where these protected products are sold, prefer easy access and low prices. Both, they argue, are achieved through low-protection, "weak" patents.

Considering that the use of patents is dominated by the "North", developing states complain that patents permit companies to have complete control of pharmaceutical

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413 To borrow the title of Charles Dickens' novel (1860-61).

414 Li & Correa (eds.) 2009, p. 5; Drahos 2002a, pp. 164-165 with reference to the work of S. Ricketson.

415 Li & Correa (eds.) 2009, p. 5.

416 See Drahos 2010, p. 286.

417 McGill 2008, p. 18.

418 *The Economist* 2010a and *The Economist* 2010b.

419 Among others, MacDonald 2002, p. 24.

inventions and genetically modified seeds. The "North", with its industries and high levels of technology, knows how to use the system, while the "South", lacking a similar industrial and technological tradition, does not. Equally important, African countries lack an economy of scale and therefore are not significant markets for innovative corporations in the "North". The incentive structure underpinning the patent system requires a sufficient return on R&D investment to make it worthwhile. Such a return, for example, on pharmaceutical research is unlikely to come from a nation in which "patients are either too few or too poor."[420]

Thinking about patents in the "South", what constitutes a fundamental problem in developing countries is that their markets are insufficient to support the kind of R&D necessary to provide the drugs required for their diseases. For one of the other critical needs of developing countries, modified seeds for growing crops in harsh natural environments and maximizing production, the picture is arguably similar. Patents require a market environment to be effective.

Arguably, this fact explains why the role of patents is limited in poor countries, where market forces are "almost irrelevant."[421] IPR legislation and policy cannot be introduced and implemented in isolation. "Complementary" law and policy "such as educational reform, market liberalization, competition policies and adequate enforcement" must be implemented.[422]

### 5.2.3 Whose Priorities?

A goal of the WTO, as stated in the Preamble of TRIPS, is to encourage and provide protection to new inventions while not inhibiting "legitimate" trade. The stated purpose of the treaty is to "reduce distortions and impediments to international trade" while promoting "effective and adequate protection of intellectual property rights" while ensuring that the "measures and procedures" enforcing IPRs "do not themselves become barriers to legitimate trade."[423] TRIPS recognized the "importance of reducing tensions" created by the unilateral pressure placed on developing countries by such mechanisms as the "Special 301" of the US.[424]

The input of developing countries was not completely ignored. For example, paragraphs 5 and 6 of the Preamble are based on text submitted by a group of developing countries. Paragraph 5, corresponding to Article 7, refers to "developmental and technological objectives. Paragraph 6, reflected in Article 66, identifies the "special needs of the least-developed country Members … in order to enable them to create a sound and viable technological base." Nevertheless, any concession to developing Members was balanced against the overall needs of the developed. While Preamble paragraph 5 permits the adoption of national IPRs in order to achieve "developmental and technological objectives," Article 8 requires that such measures should be "necessary" and "consistent" with the provisions of TRIPS.

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420 *EU Global Health* 2010, p. 5.

421 de Carvalho 2005, p. 25. Recognition is given to this in Article 65 of TRIPS ("Transitional Arrangement") which provides additional implementation time to countries which are "in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system."

422 Claessens 2009, p. 554.

423 Preamble to TRIPS.

424 See for the "Special 301": Chapter 3, para. 3.2-3.3.

As a result of this complexity, and the attitude of the developed Members, the TRIPS Agreement has come to symbolize a clash of needs. Developing countries, generally the purchasers rather than the producers of patented products, argue that IPRs as shaped by TRIPS negatively affect their development by, for example, limiting access to technology and increasing the price of patented products.[425] It is believed that if such a price increase implicates a product such as pharmaceuticals it can – directly or indirectly – produce significant health consequences.[426,427] It is noted, however, that price is not the only determinant of access and availability (see Chapter 4, para. 4.6) and that infrastructure issues in developing countries are no less an obstacle.

With regard to provisions in TRIPS that allow members to take action where national health is concerned, it is noted here that even such "flexibilities" ostensibly designed to facilitate action on public health issues are not readily utilized by developing countries (see Chapter 3).[428]

### 5.2.4 Global Pledge vs. Commercial Interests

The observed imbalance can be discussed from yet another angle. The global pledge – for example, the UN Millennium Declaration of 2000 – taken by the governments of developed countries to eradicate hunger and poverty and combat life-threatening diseases in Sub-Saharan Africa and other areas, at some point conflicts with one of their fundamental tasks of protecting the commercial interests of their own industries that control both the raw materials and their products. This creates tension in international development policies and trade policies and measures (see Chapter 1, para. 1.2.11). A well-known example is the heavy subsidizing by the EU and the US of their domestic agricultural sectors,[429] hampering exports of African agricultural products and thereby impacting economic growth.

Another example is the seizing of generic drugs in transit from India to Latin America and Africa by European IPR enforcement authorities. Seizures taken by the Dutch customs authorities in the past years, among others involving a consignment of Indian-made medicines destined for distribution at clinics in Nigeria, particularly reflect the 'friction' between the EU legislation to counter fake medicines and the WTO rules providing for freedom of transit of goods.[430] Shipments of drugs that were legal in the exporting and importing countries were stopped because they were not recognised in the EU. Reasons were

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425 Among others, Homere 2007, p. 337.

426 See, generally, Walker 2001, paragraphs 3-4, for example.

427 Patents are not the sole means of "protecting" new drugs. Test data for a new drug receives five years of exclusive protection while test data for a new indication of an existing drug receives three years of exclusive protection in the US. (21 U.S.C. 355(c)(3)(E)(ii)-(iii) (2000) referenced by Kapczynski *et. al* 2005, footnote 46). This kind of "protection" is not limited to the US.

428 See Chapter 4, para. 4.6 for the picture in Sub-Saharan Africa. Relatively advanced India and Brazil, experienced in manufacturing generic drugs, are known challengers of patents on drugs and may therefore be called exceptions to the rule. See Box I-20: *Natco Pharma case India (2011)*, Chapter 4, para. 4.6.

429 See for the (staggering) numbers the following helpful online sources: < http://farmsubsidy.org/ > (EU) and the Farm Subsidy Database < http://farm.ewg.org/ > (US) (accessed on 1 July 2011).

430 'Recent Dutch seizures of generic drugs add fire to the WTO dispute regarding seizure of goods in transit' , 6 May 2009, < http://eccustoms.blogspot.com/2009/05/recent-dutch-seizures-of-generic-drugs.html> (accessed on 1 July 2011).

(alleged) infringement of patents in the EU by the generic medicines – of substantial value[431] – and safety concerns (health). The seizures increased concerns over access to essential medicines. The EU and India ostensibly resolved this dispute in late 2010, the EU promising that transports passing through will only be checked for counterfeiting.[432]

Further, several components are necessary for commitments to the MDGs to be fulfilled, not the least of which is funding and carrying out the essential R&D necessary to provide the medications, vaccines and, in the area of food security, modified crops. (See Box I-23).

One of the main problems is where to obtain the funds. Governments do not as a rule take upon themselves the research, development and production of technological products such as genetically modified seeds and medicines. In part, this is left to the laborious, high-risk and very costly efforts of companies operating in the innovation arena.[433] The way to reward these companies, other than to reimburse them with state funding, is to grant control of the inventions for a limited time.

And yet, funding is not always the biggest issue. For example, organizations such as the AIDS Fund are known to have considerable war-chests. For example, organizations such as the AIDS Fund, which stresses uniting "together as advocates, community partners, community-based organizations and educators," has a considerable war-chest.434 In theory, such organizations may collect enough financial means to fund expensive R&D research. Another example is a "prize fund" for generating medical R&D, under which a specific amount of money is awarded to the first firm that can meet a specified medical (or other) target – implying a competitive environment and shared responsibility for necessary R&D.[435] In addition, examples may be observed of multinational corporations that show willingness to share some of their reservoir of R&D data, such as through the Medicines Patent Pool,[436] but concerns over (unfair) competition remain strong.[437] So-called "open source" initiatives for designing medical treatment include an interactive platform called Open Source Drug Discovery (OSDD) where scientists contributing research can receive monetary or non-monetary rewards.[438] In other words, various (civil society, public-private) initiatives create exceptional possibilities and therefore power.

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431 Almost half of India's drug exports worth USD 22 billion are generics, as reported by *The Economic Times* on 6 April 2011, < http://articles.economictimes.indiatimes.com/2011-04-06/news/29388612_1_multilateral-intellectual-property-agreement-generic-drugs-valid-patents> (accessed on 1 July 2011).

432 The member countries might have to amend their national laws in order to be compliant. See < http://www.indianexpress.com/news/india-eu-settle-generic-drug-seizure-issue/694259/> and < http://www.in-pharmatechnologist.com/Industry-Drivers/EU-India-resolve-generic-drug-seizures-dispute-reports> (accessed on 1 July 2011).

433 Universities play a role too in R&D and inventions. To emphasize the point, an academic researcher was responsible for inventing an important drug cocktail used to treat HIV; as mentioned by Boldrin & Levine 2008, p. 227.

434 <http://www.aidsfund.org/2010/11/22/naf-aids-action-merge-to-form-aids-united/> (accessed on 1 July 2011).

435 The so-called Medical Research and Development Treaty, in connection with the WHO; described by Trezza & Wong 2011, p. 371.

436 Website <http://www.medicinespatentpool.org/> (accessed on 1 July 2011).

437 As for example observed by Dutch reporters, Engelenburg 2010, p. 11 and Uitdehaag 2010, p. 7.

438 The OSDD in India. As described by Trezza & Wong 2011, pp. 374-375.

**Box I-23: *Global Pledge: Brief Review of MDG Efforts*[439]**

*Almost all developing countries appear to have tailored the MDGs (or their associated targets and indicators) to their national conditions and priorities.*[440] *While this is undoubtedly a positive development in the short time-span since 2000, the question is of course: does it work? Here the problem reveals itself that getting evidence on the effect(iveness) of national MDG policies proves an arduous task. Reportedly the overwhelming majority of African countries, for example, do not yet have data available.*[441] *However, this is now improving with the aid of a series of country-based progress reports on the MDGs, published under the coordination of the UN.*[442]

*From these sources it appears that, as regards progress, the picture is mixed across developing countries. At least prior to the global banking and economic crises, the World Bank has found, many developing countries had made considerable progress in reducing extreme poverty thanks to an extended period of economic growth.*[443] *Thanks to rapid growth, especially China and East Asia had already halved extreme poverty. Although Sub-Saharan Africa as a whole remained behind, poverty had also been falling rapidly there. Progress on the other MDGs, however, was uneven across the indicators and regions: progress related to human development (child mortality, hunger and nutrition, HIV/AIDS, gender equality beyond primary education) had been much slower than MDGs related to education for example, most notably in Sub-Saharan Africa.*[444]

*International efforts have been stepped-up to achieve the Goals by 2015. Although there is reason for cautious optimism, there is still much left to be desired. Strong language is used in the 2010 UN Report on the Millennium Development Goals: it bluntly states that "without a major push forward, many of the MDG targets are likely to be missed in most regions."*[445] *Similarly, the European Commission has stated that progress towards the three health MDGs 4, 5 and 6 has been "uneven and largely off track in most developing countries."*[446] *For example, while the number of people receiving antiretroviral treatment in developing countries "has increased ten-fold in the last five years", HIV/AIDS continues to be the "primary single cause of death in Sub-Saharan Africa."*[447]

*It seems fair to note, however, that the time-span since the Millennium Declaration is short, considering the ambition to achieve no less than raising living conditions globally. Even though the timeline has helped to create the momentum among political leadership, since 2000*

439 See introduction of MDGs, in Chapter 1, para. 1.2.4.

440 Beyond Midpoint 2010, p. 10 reports that 86% of developing countries has done so according to a global survey undertaken by the UNDP.

441 UNDP Millennium Development Goals Country Report South Africa 2010, pp. 2-3.

442 Links can be found on the UNDP website: <http://www.undp.org/mdg/reports.shtml> (accessed on 1 July 2011). In addition to the periodic country reporting MDG monitoring is also taking place through annual reports of the United Nations Secretary-General and international organizations such as the World Bank - see its *Global Monitoring Report 2010*.

443 As found by the World Bank, Global Monitoring Report 2010.

444 Global Monitoring Report 2010.

445 MDG Report 2010, p. 4.

446 EU Global Health 2010, p. 3.

447 *Idem.*

*events such as the financial and economic crises in the developed world have led countries to adjust their priorities.*[448] *For these and other reasons, achievement of the goals has been hampered by "unmet commitments, inadequate resources, lack of focus and accountability, and insufficient dedication to sustainable development."*[449] *It is noted in this respect that the MDGs, while important for the reasons outlined above, represent an approach to development that believes the global community's task of raising the conditions in developing countries can be achieved by breaking that task down into goals, targets and indicators.*[450]
*While this project focuses on MDGs related to food security and health, in fact the MDGs are interrelated and the success of one must be associated with success of another. For example, although the focus in this report is on patent issues related to pharmaceuticals as a factor in achieving reduction of HIV/AIDS, tuberculosis, and malaria, it must be recognized that failure to empower women (another MDG), for example, will prevent successful treatment of these diseases (see Chapter 1, para. 1.2).*

### 5.2.5 Implementation Assistance Problematic

Initially, developing countries resisted joining TRIPS, and later, compliance with TRIPS, for example arguing that they lack the resources to monitor and enforce IPRs (see TRIPS background, Chapter 3).[451] Implementation assistance was offered to developing countries, which looked reasonable enough on paper. The problem with the assistance that was provided, however, was that developed countries continued their political agenda – they never forgot their own interests and did not hesitate to put them on the table.[452] In a recent empirical study, various types and cases of pressure as regards TRIPS implementation were brought to light. "The TRIPS implementation game was played by a range of stakeholders with intense interests in what happened "on the ground" in developing countries. In the context of global debates about the terms of the TRIPS Agreement and IP regulation more broadly, economic and ideational power were used by a diverse array of stakeholders to push for rapid and strong TRIPS implementation or to advocate for more-tailored, development-oriented approaches to national IP reforms".[453]

One example is mentioned here. Technical assistance and capacity-building assistance were offered to developing countries as a 'side-package' during the TRIPS negotiations, and laid down in Article 67 TRIPS. Initially, the purpose was to assist developing economies (i) in implementing the minimal IPR standards prescribed by TRIPS and (ii) in making the most of the flexibilities allowed by TRIPS. Later, under the pressure of US negotiators the emphasis shifted to a 'demand-driven' program putting the onus on 'client' countries to ask for specific

[448] MDG Report 2010, p. 4.

[449] *Idem.*

[450] Critical of the way developed countries deal with their moral responsibilities with regard to poverty-reduction including the MDGs: Pogge 2008, pp. 1-32. Easterly 2008, p. 10 criticizes the UN MDG Project for talking about "planning" the growth rate using a "mechanical relationship joining aid, public investment, and growth".

[451] See on developing countries' resistance with regard to TRIPS compliance, for example Homere 2007, p. 337.

[452] For example, expansion of IPRs, enforcement included, has been a goal of US foreign policy in implementing TRIPS and other trade-related agreements, Gollin 2008, p. 57.

[453] Deere 2009, p. 186.

technical help.[454] This approach appears to have ignored the needs of developing countries. Although external (technical) help with implementing TRIPS in national laws has been offered, and in some cases, actually utilized, such assistance, whether by developed countries or organizations such as WIPO and WTO, has been subject to political and economic priorities stemming from the needs of developed states. TRIPS implementation has been characterized as an "intense political game" in which developed countries sought strong IPRs and rapid compliance while the developing countries preferred a "tailored, development-oriented approach."[455]

It is noted that the failing assistance does not mean that developing country governments are completely helpless in the face of developments in international IPR. Non-state actors such as in particular non-governmental organizations (NGOs) fulfill various functions for developing countries and play a role in guiding the development and IPR processes.[456] One example is the international not-for-profit organization PIIPA (Public Interest Intellectual Property Advisors) that provides free legal advice to developing countries that seek to promote health and agriculture.[457] This kind of cooperation arguably mitigates some of the downsides of the international IPR system for those developing countries that do not have the technology and capabilities yet to benefit from the international IPR system.[458] [459]

### 5.3 Future Scenarios

TRIPS did much to raise public awareness and debate over the relationship between IPRs and the public interest, by inserting IPRs into the international trade agenda.[460] No consensus exists on the critical point where protection of private interests ceases to be a gain and starts to become a loss for innovation and the public interest.[461] That point is ultimately a matter of choice, reflected in the nature and goals of IPRs as legal instruments. "The interested public is not a passive recipient in the equation, but is increasingly active in defining this balance."[462] This is happening in the debate on IPR in developing country' contexts, too. If this Chapter was concerned with power differential, the engagement of public-interest actors may be called a "power shift". Several groups and organizations in recent years have undertaken "scenario planning", i.e., have considered a variety of possible futures (not predictions) for IPR. One example is a collection of ideas by the European Patent Office called *Scenarios for*

454 Maskus 2009, p. 166.

455 Deere 2009, p. 304.

456 As shown by Matthews 2011.

457 Website < http://www.piipa.org/> (accessed on 1 July 2011).

458 As was mentioned in Chapter 4, the potential to benefit from TRIPS-compliant IPR systems depends to a significant extent on the presence of advanced technology and manufacturing capability, and skilled human resources, as found by Odagiri *et. al* (ed.) 2010, pp. 420, 424, 428.

459 More generally, independent expert-networks on IPRs in developing country' contexts can be helpful to governments and other stakeholders seeking information. One example is the network centered around the *IP Handbook* 2007 and international case studies, see <http://www.iphandbook.org/handbook/case_studies/ > (accessed on 1 July 2011). Online networks are especially important considering that printed publications are costly and require shipping, which can be problematic.

460 Gollin, Hinze & Wong 2011, pp. 336-337.

461 Gollin, Hinze & Wong 2011, p. 337 referring to B. Wallis (2006).

462 *Idem.*

*the Future*, discerning between dominant drivers for IPR regimes.[463] Scenarios help governments to prepare for the (legal-policy) choices they face and set out a course. As not all scenarios put (equal) emphasis on the perspective of development, some ideas are more helpful to developing countries than others.[464]

At the global level, IPR protection remains at a crossroads and it is difficult to predict where it will go.[465] A variety of approaches can be taken by governments and civil society, at various levels. Possible futures include either a gradual expansion of IPRs as countries come into compliance with TRIPS or a broad expansion of protection of all types of IPR around the world – a development supported by US foreign policy, for example.[466] Another alternative is a "rollback" or "reduction" in IPR protection,[467] or perhaps some IPRs more than others. There are already some developments pointing in that direction with regard to patent – for example, developing countries pushing for expansion of the instrument of compulsory licensing for national health reasons; segments of the research community advocating broad exemptions of scientific research from patent infringement; and developing countries rich in biodiversity adding restrictions on patents by requiring the applicant to identify the source of any genetic material or TK used in the invention.[468] Such a rollback or reduction might come from a redefining of IPR in the light of social goals including development needs.[469]

The *social purpose* of IPRs and enforcement could then be made central in discussions on international IPRs in connection with access to medicines and to seeds.[470] Any such adjustment of course, leading to more prominence of social values in IPR laws and principles, is likely to require more flexibility – autonomy, or self-determination – for individual country policy-makers than the dominating stakeholders in the "North" presently allow.[471]

### 5.4 Conclusion

The "power differential", i.e. the different strength of influence of "North" and "South" countries, has resulted in developed countries dominating the process from negotiating the international IPR regime to applying the rules largely as they see fit.[472] In order to overcome this effect, a more balanced approach is needed that acknowledges but does not abuse the differential in power – economic, trade, negotiating power. This is a tough goal to achieve. It requires sacrificing some of developed countries' self-interest in turn for greater fairness,

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463 *Scenarios for the Future* 2007, p. 5 (overview) discerns between the following dominant drivers: business, geopolitics, society, and technology.

464 For examples Gollin, Hinze & Wong 2011, particularly pp. 336-337 is referenced here.

465 This section draws on Gollin, Hinze & Wong 2011, pp. 358-359.

466 Gollin, Hinze & Wong 2011, p. 358 referencing Gollin 2008, 57.

467 Gollin, Hinze & Wong 2011, p. 359.

468 Gollin, Hinze & Wong 2011, p. 359, including footnote 56 (recent decisions of the US Supreme Court indicating that it is becoming harder to obtain and enforce patents in the US).

469 Gollin, Hinze & Wong 2011, p. 359.

470 Paras. 5.3-5.4 of this Chapter, and Muzaka 2011, p. 136.

471 Compare the limited gains for developing countries so far in the ongoing debate in the framework of the Development Agendas (WIPO, WTO).

472 On the background another motive played a role, related to the challenges posed when national legal diversity meets economic interdependence (Pollack & Shaffer 2009, p. 279); it seems natural for powerful economies to exploit their power by using international agreements to their advantage.

which is expensive. This could also impact international development policy. Developed countries are reminded however "that their long-term security and prosperity are, in a large part, linked to successful economic development," and that "poverty tends to breed the resentment and violence that undermine the security interests of developed countries"[473] – providing development support therefore serves their self-interest too.

The MDGs, creating focus and momentum in international development efforts, have helped developing countries in Africa and elsewhere to control ("own") their national development agenda.[474] Almost all developing countries appear to have tailored the Goals (or their associated targets and indicators) to their national conditions and priorities.[475] This may reflect positively on their overall stronger national agenda-setting and representation at the international stage. In future, the development perspective of developing countries might lead to a redefining of IPR at the international or national level, but such a development is likely to conflict at some point with the economic interests of developed country governments and industries.

To illustrate the point, the EU, an important trade and development partner to African countries, was heavily criticized a few years ago for its "TRIPS-plus" IPR demands in negotiations on Economic Partnership Agreements (EPAs).[476] It has been argued that the EU should remedy this power unbalance and make an effort to correct this.[477] Such reforms, if they materialize, might also permit more and broader usage of developed-country knowledge for development purposes.[478] For example, at the moment the EC seems committed to offering fairer terms to its trade partners in Africa. In the course of EPA negotiations with the Cariforum[479] region, it stated: "As regards intellectual property rights, the agreement expressly notes that their enforcement should take into account the development needs of the Cariforum countries and provide for an adequate balance of rights and obligations between right holders and users. In this spirit it is clearly stated that the capacity of the parties to promote access to medicines should not be impaired. (…) Cariforum can fully use the flexibilities of the TRIPs Agreement and in particular the granting of compulsory licenses to facilitate access to affordable medicines."[480] Even if they are only words, such expressed intentions are a good start. Ultimately, however, the question is how the EU and others will react to voices demanding or claiming the right to develop IPR regimes

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473 Lee 2006, p. 165.

474 Reported in: Beyond Midpoint 2010, p. 8.

475 Beyond Midpoint 2010, p. 10 reports that 86% of developing countries has done so according to a global survey undertaken by the UNDP.

476 See, for example, <http://www.ciel.org/Publications/EPA_Synthesis_4June07.pdf> (accessed on 1 July 2011). An analysis of EPAs between the EU and African regions is provided by Gathii 2011 (forthcoming).

477 <http://aprodev.eu/files/Trade/2010_07_aprodev_submission_ecfuturetradepolicy.pdf> (accessed on 1 July 2011), referring to Cotonou Partnership Agreement Article 37.6.

478 Henry & Stiglitz 2010, p. 242.

479 See <http://www.crnm.org/index.php?option=com_content&view=article&id=276&Itemid=76> (accessed on 1 July 2011).

480 See <http://trade.ec.europa.eu/doclib/docs/2008/october/tradoc_140978.pdf> (accessed on 1 July 2011), a fact sheet describing the content of part of the CARIFORUM-EC EPA. African criticism on current proposals remains, among others on the choice to offer African countries reciprocal preferences only, while other non-EU European countries, *i.e.* Moldova and Balkan countries reportedly were offered a more favorable deal (Khor 2010).

consistent with social goals such as human development needs in health, food security and education.[481] [482] If the driving political forces behind TRIPS - the US, the EU - fail in this respect, "global" IPR standards will probably never really mature.

[481] Compare Gollin, Hinze & Wong 2011, p. 359.

[482] This process is already underway, if one takes into account the Development Agendas in the framework of WIPO/WTO (Chapter 3), and "isolated" cases of patent law 'diverging' from the international standard (India, with more options for obtaining licenses for patented pharmaceuticals).

## CHAPTER 6 CONCLUSIONS

**1. The international IPR system, like any legal system, can only be successfully utilized for the purpose for which it was designed.**

(a) TRIPS, recognized as the cornerstone of the modern international IPR system, has its origins in the need felt by the major developed countries (who went on to dominate the process by which it was created) to protect their intellectual property worldwide.

(b) The international IPR regime was created primarily for the purpose of protecting the intellectual property developed and owned by persons based within developed countries.[483] To achieve their goal, a universal harmonization of national IPRs was inaugurated (TRIPS) in conjunction with a means of enforcing these international rules (WTO Dispute Settlement Procedure).

(c) The international IPR system, its purpose being to facilitate trade by establishing international IPR standards, has primarily benefitted the international trade of the multinational corporations generally based in the "North". Developing countries in Sub-Saharan Africa have been unable to resist this movement and enforce their own agendas as they often lack the necessary (IPR) infrastructures and economic power. Additionally, they must contend with the burdens of inadequate public health systems, poor food security and sub-standard education, all of which are essentially included in the Millennium Development Goals (MDGs).

(d) The international IPR system was not created for the purpose of fostering development although, responding to concerted efforts on their part, some concessions were made to developing states. While some components of the international IPR system could be modified to accord with recognized developmental goals, to expect IPRs to be the "drivers" of universal development is unrealistic.

**2. Broadly considered, the IPR system emerged from the Anglo-European-American economic and legal systems with their emphasis on rights of the individual and the rewards of private ownership.**

(a) Because of this, the international IPR system is not readily accepted by communities that have different concepts of "ownership", i.e., communal ownership, stewardship. The different perspectives of ownership (and inventorship) prevalent among developing nations meant that the products integrally tied up with their own culture and history ("Traditional Knowledge") do not readily lend themselves to the IPR systems derived from developed countries of the North. As significant modification of the current international IPR system is uncertain, an alternative form of trade protection will become necessary.

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[483] The term "person" is used in the legal sense *i.e.*, an individual, a company or a corporation that either owns or has been assigned the rights to an invention.

(b) In terms of IPRs, MDGs 1 and 6, the main focus of this report, implicate patents predominantly. Patents are the form of IPRs most relevant to inventions in the fields of pharmaceuticals, medical devices, biotechnology and genetically modified seeds.

**3. The developed countries, particularly those with significant economic power, have utilized and will likely continue to utilize the international trade and IPR system to suit their purposes.**

(a) Since pirating of technology began to reach significant proportions in the 1970s and 1980s, the governments of developed countries, having been heavily lobbied by affected sectors of industry, have been the driving forces behind international IPR standards. The outcome of their efforts resulted in the TRIPS Agreement although the final product was not everything developed countries hoped for. As a result, and because developed countries wanted higher IPR standards beyond the "minimums" of TRIPS, additional agreements (so-called "TRIPS-plus") were negotiated following varying degrees of political and economic pressure. Areas such as unfair competition and trade secret legislation were included. Developing countries have accepted these agreements either through the promise of some form of trade concession or the threat of trade reprisals.[484]

(b) IPRs, as they came into being in Europe and the United States, function best in the environment for which they were created: industrialized countries with market economies and substantial infrastructures. Developing countries in Sub-Saharan Africa are in a different situation. Assuming that they will have to introduce international IPR standards to be competitive in world markets and obtain the pharmaceuticals and seeds they need, the question is: when is the time right in their development trajectory to introduce these IPR standards, and what should these standards should look like? TRIPS attempted to deal with at least part of the question by means of delayed implementation and the flexibilities.[485] Regarding the second part of the question, developing countries were faced with just the (one) model the agreement ultimately offered, based on the economic and legal systems of industrialized countries.

(c) Whether achieved by means of "forum shopping" (seeking out the most appropriate international forum for their purpose) or "bilateralism" (entering into trade agreements that couple increased IPR demands with threats of trade retaliation), the world economic powers dominate and will continue to dominate the international IPR system.

(d) Dependency on international funding limits the degree to which developing countries can challenge the status quo. For example, while it is possible in theory for developing countries to utilize international organizations such as the WTO (Trade Policy Review Body, Council for TRIPS) or WIPO as a means of challenging major developed countries, their power to effect

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484 Deere 2009.

485 What is meant here is (1) a formal, temporary exemption from TRIPS for least-developed countries (LDCs), and (2) certain exceptions to TRIPS provisions known as the "flexibilities". On the African continent, at present thirty-three countries are considered LDCs according to the UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, source < http://www.unohrlls.org/en/ldc/related/62/> (accessed on 1 July 2011).

change is ultimately limited (unless of course they are able to unite in sufficient numbers to impose their wishes via voting blocs - assuming that developed countries have not already moved to the next, more useful, forum).

(e) The policy of individual developing states not being forced but rather encouraged to have direct input into national and international IPRs is consistent with United Nations Development Program (UNDP) recommendations regarding the MDGs. In a recent publication, the UNDP stresses the importance of the "local governance institutions, civil society and the private sector" noting that "strategies that are locally developed and based on broad national consensus, (…) tend to lead to more effective and sustainable development outcomes."[486]

(f) Further, the "right to intellectual property must be understood in the context with the right to development and self-determination. Such an approach would delegitimize the myth of a universally valid intellectual property system and protect the right of developing countries to establish intellectual property regimes that reflect their unique socioeconomic and cultural norms and that are consistent with development objectives." But even if this is more than developing countries enjoy today, it is probably not enough, as "nothing short of a comprehensive economic and social reform package nurtured and implemented in a politically stable environment under the rule of law will release Africa's potential for development."[487] Reform of this magnitude is significant in a part of the world where several governments fail to provide safety for their populations, much less achieving the MDGs.

(g) A significant modification of the established international IPR system is uncertain but not impossible, as voices emphasizing a different fairness are many. For example, recent works of scholarship argue openly for overcoming the historic imbalance in TRIPS and reconciling IPR laws with fundamental societal needs, both in developing and developed countries.[488] International IPRs, temporary monopoly rights based on certain concepts, values and goals, mirror choices that need to be evaluated and adjusted to keep or (re)gain support, both in developing and developed countries.

**4. Lack of coherence of development goals (including MDGs) and IPR goals.**

(a) Achieving MDG targets requires both the input of the developed states and the cooperation of developing states. As participation in the international IPR system has become a requirement of any form of international trade, the IPR system of developing countries must find a role within the – MDG-based – development strategies as outlined by the UNDP.[489] Particularly relevant are the goals of expanding local policy options and choices, and strengthening national capacity.

(b) While this project has focused on MDGs related to food security and public health, MDGs are interrelated and the success of one must be associated with success of another.

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[486] UNDP 2010, presenting eight action points to achieve the MDGs.

[487] Quotes in this section from Okediji 1996, pp. 315-316.

[488] An example being, just published, Kur (ed.) 2011.

[489] See <http://www.undp.org/mdg/roles.shtml> (accessed on 1 July 2011).

(c) The creation of TRIPS, and subsequent TRIPS-plus agreements, has focused on trade specifically. Development was, at best, a secondary consideration. The drive for IPRs has not been accompanied by a similar drive for development in developing countries. Directing coherent policies of trade and development, and thereafter implementing them, is a duty of governments, in collaboration with international organizations, such as the United Nations.

(d) As noted, the underlying problem is a lack of coherence, e.g., between the policy goals and implications of the MDGs and the international IPR regime.

(e) Developing countries have started to meet and negotiate as groups under the leadership of the more powerful – e.g., India, Brazil, South Africa – to pursue a development-friendly agenda within the international IPR system. Topics include various aspects of IPRs such as biotechnology, competition law (although further agreement depends on a consensus among developing states). Another component in the politics of international IPR are non-governmental organizations ("NGOs"), which fulfill various functions for developing countries including ensuring supplies of medications, availability of food, and of particular relevance to this report, guiding their development and IPR processes.[490]

### 5. IPRs cannot be successful where there is no solid legal, economic and educational infrastructure

(a) For developing countries to participate in the international IPR system they need to create an appropriate national infrastructure involving a range of legislative, executive and judicial government departments. As is typical in many areas where countries were eager to introduce TRIPS-inspired IPR legislation, in Sub-Saharan Africa IPR laws were drafted before the supporting policies and infrastructure was in place.[491]

(b) IPRs, in isolation, have little value, if they are not supported by a broader set of effective laws, coordinated policy programs, and functioning government agencies.[492]

(c) Developed countries have long been interested in higher levels of enforcement and have sought various means of achieving this including requiring additional rules, and threats of retaliation.[493] In contrast, developing countries are more concerned about the additional burdens involved in complying with these demands, as they require additional resources to support these demands. Developed country governments face a dual responsibility – a domestic one, towards their industries, and internationally, towards developing countries they are in a partnership with (although of course it is often hard to separate the impact of these two forces on each other).

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490 See on the importance of NGOs in facilitating developing countries, Matthews 2011.

491 As discussed in detail in this report, countries were induced to change or introduce IPR legislation, by a combination of "carrots" (better tariffs, preferential treatment etc.) and "sticks" (threats of trade sanctions).

492 As was discussed in detail in this report, Chapter 4, with references.

493 Among others, Deere 2009, p. 220 ff.

(d) Africa's infrastructure would best be addressed in a regional manner if countries are to reap the benefits of economies of scale, develop intra-African trade and enhance competitiveness in the global economy.[494]

(e) The wide range of challenges that different individuals and communities face, and the diversity of their priorities, leads to the conclusion that a single policy approach to IPRs is neither appropriate nor possible.[495] Equally impossible is analyzing the influence of IPRs on development in general, as the context has to be specified, e.g., the market sector.[496]

(f) The more advanced a developing country becomes – well-known examples of countries with established technological and manufacturing capability and skilled human resources are China, Brazil, India and South Korea – the greater its interest in IPR protection for its own industries.[497] It is expected that fast-growing and innovating China will soon develop a local use for IPR. For most Sub-Saharan countries advanced levels are unattainable for the foreseeable future. This means that most parts of Sub-Saharan Africa are essentially excluded from the use and benefit of implemented IPR systems.

(g) Therefore, in the Sub-Sahara region TRIPS-compliant national IPR systems might benefit foreign rights holders and foreign rights holders only, while not achieving much for local use, which the mere presence of a (patent) system does not create. An understanding of the mechanisms of innovation and imitation of technology and methods in specific sectors in developing countries can help those countries to determine national IPR policies that work for them.

### 6. Distinguishing between real and perceived obstacles and opportunities to IPRs

(a) The 'developed' versus 'developing' scenario initially conceptualized in this report may have proven to be simplistic. There are too many players (stakeholders) in the game, not to mention the differential in the levels of development. It is equally simplistic to discuss the role of IPRs in developing countries in general.

(b) The relationship is between IPRs and development, therefore, is complex. While some positive effects of the international IPR system may be felt by all developing countries, the role of IPRs in developing countries depends on its context[498] – the particular sector, the country and/or region, and the conceptual choices as regards IPRs. There can be a positive relationship between IPRs and development in technologically advanced developing countries which have high-level industries and manpower, while such a relationship cannot exist in less-developed countries in the absence of local use for a TRIPS-compliant system and functioning institutions.

494 MDG Africa Steering Group 2008, pp. 16-17.

495 S. Fakuda-Parr (forword) in: Wong & Dutfield (eds.) 2011, p. xix.

496 Odagiri *et. al* (ed.) 2010, p. 423.

497 Conclusion drawn from Odagiri *et. al* (ed.) 2010, pp. 420, 424 and 428.

498 Odagiri *et. al* (ed.) 2010, p. 421.

(c) The importance of IPRs for innovation and economic development in developing country contexts is widely assumed, but how this relationship works, or even whether it works, is unclear.[499] This uncertainty impacts (international assistance with) the implementation of the international IPR regime and also international development policy. In addition, innovation is not merely a matter of technology, and is to be seen as a culture-dependent concept (personal vs. communal).[500]

(d) While the TRIPS Agreement intended to establish a universal standard of IPRs aimed at enhancing international trade, the outcome of this process was not quite as anticipated both for the developed nations who pushed through TRIPS and the developing states that were required to implement it. Developing countries have trouble setting up appropriate infrastructures and developed countries continue to experience the absence of adequately functioning IPR systems. In Sub-Saharan Africa this situation is unlikely to change soon.

(e) Patents, without the appropriate economic balances such as appropriate and enforceable anti-trust legislation, may hamper MDGs as patents involve control – of the market price, the invention, and related R&D and data. But while patents dominate the controversy with regard to access to medicines and seeds, a developing country's infrastructure is at least as important for access.

(f) According to a comparative study, having a functioning IPR system is less relevant to developing countries in attracting foreign investment and international trade partners than usually believed.[501]

(g) Patents are less essential to maintaining – costly – drug development efforts than often perceived.[502] Higher standards in patent protection "do not necessarily induce the development of new pharmaceutical inventions," as there is increasing emphasis in companies' R&D policies on "new therapeutic uses for known drugs and minor modifications to them" (so-called 'me-too' drugs).[503] This is considered less innovative than developing new pharmaceuticals, which remains costly.

(h) Even though the international IPR system has (had) negative effects on developing countries, they are not helpless victims. For example, increased "South-South" cooperation and the formation of regional alliances, have given developing countries more power to cope with the global governance of IPRs. In addition, while Sub-Saharan Africa has some clear common concerns, it must be acknowledged that the 47 countries in that region have individual characteristics and circumstances, necessitating specific analysis and policies.

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499 In detail on the workings of innovation in IPR contexts, Gollin 2008; Greenhalgh & Rogers 2010.

500 See for example Wong & Dutfield (eds.) 2011, among others on innovation in farming communities in developing countries.

501 Odagiri et al. (ed.) 2010, p. 420.

502 Chamas, Prickril & Sarnoff 2011, p. 64.

503 Chamas, Prickril & Sarnoff 2011, pp. 64-65.

## 7. How to work with and in the system?

(a) The perspective of developing countries has gained momentum in the international IPR debate, due largely to the Development Agenda efforts. Evidence is emerging that the system as it is favours industrialized countries over developing countries.[504] There is no international consensus however on whether to change the international IPR system and, if so, how. Allowing and assisting developing countries to make use of the exceptions (flexibilities) in the international IPR system might bring relief – even though not everyone is convinced of the freedom to operate when it comes to setting up patent systems.[505] But it will not create a local use for IPRs in these countries nor take care of wider innovation and development issues. But deeply thought-through input by legal scholarship will help to understand how exactly the existing international IPR system could be rebalanced taking care of the different and multifaceted contexts of countries.[506]

(b) As regards making IPRs work for developing countries in the future, a distinction can be made between actions that could be taken at the global level, the regional level or the national level. For example, influencing the dynamics of IPR negotiations in trade agreements, and forging coherence of MDGs and goals related to international trade including IPRs, are aspects to be dealt with at the global level. Regional cooperation in Sub-Saharan Africa is necessary for improved infrastructures in the region, for model laws, and consensus on trade negotiations. At the national level policies are (or should be) established on innovation and development, explaining how IPRs support these policy goals. The latter process is aimed at supporting local use of IPRs (depending on available infrastructure and a viable economy).

(c) Positive experiences with IPR tend to be found in developed countries where high-tech research sectors can benefit (see 6, (b), above). Developing countries in Sub-Saharan Africa are not in a similar position and the mere transfer of technology will not change that. Transferring the knowledge of how to use the technology and adapt the technology to local circumstances and markets is equally important.[507] Given the rapid changes in patentable technology, an IPR system associated with technology transfer must be able to adapt to the needs of rapidly changing technological progress.

## 8. Conclusions: other aspects

(a) Approaches such as that of the African Union Commission (AUC) which has resolved to act within the framework of the New Partnership for Africa's Development (NEPAD) to develop a pharmaceutical manufacturing plan for Africa that would encourage the local production of essential medicines.[508] IPRs would play a role at several levels within a plan of this kind. For

504 Hu & Png 2010); Odagiri et al. (eds.) 2010.

505 Drahos 2010, p. 286: "(..) even a modest use of the principle of compulsory licensing in relation to medicines attracts a 'shock and awe' response from the international pharmaceutical industry (..)".

506 E.g. Kur (ed.) 2011; Wong & Dutfield (eds.) 2011.

507 Foray 2009.

508 UNIDO 2010.

example, there would need to be mechanisms to protect against substandard and counterfeit drugs.[509]

(b) Technology and information transfer "North-South", e.g., between (public) universities in the "North" and both universities and industries located in the "South", is problematic for various reasons. (1) In those situations in which such transfers implicate intellectual property ownership, it is often debated what protections are appropriate, e.g., licensing, patent pool agreements or even a system utilizing the concepts of "open source". (2) Industrialized countries supporting technology transfer programs tend to emphasize the enforcement of the IPRs of their companies, rather than putting development goals first.[510] (3) The "North" is not living up to its commitments under TRIPS to make technology available for development purposes, because of economic concerns.[511]

(c) While the future is open, one of the scenarios currently considered is a redefining of IPR in the light of social goals, such as human development needs in health, food security and education.[512] Any such course adjustment will require more flexibility for individual country policy-makers than the dominating stakeholders in international IPR presently allow.

## 9. Following the conclusions: recommendations

(a) Multinationals, universities and other institutions that control intellectual property protected products that might be of benefit to the "South" should be encouraged to explore alternative systems of protection. These might include various licensing mechanisms, patent "pooling," and even creative forms of "open sourcing" that would allow rights holders some control of their intellectual property.

(b) Developed countries, particularly those with established sophisticated IPR systems, should be encouraged to cooperate with developing countries seeking to upgrade their patent offices and IPR administrations in general. This could include a number of aspects including direct training of examiners, providing access to their patent databases, help with searching and other aspects of patent examination. Similar efforts could be used for the training of those involved in enforcement such as judges and lawyers and border and customs officials.[513]

(c) This report recommends a reconsideration of the development and implementation of IPRs. The international IPR system, as currently constituted in TRIPS can be viewed as "pro-North" in the sense that it best suits developed countries. The implementation of the international IPR system should take into account the needs of developed countries by modification of TRIPS obligations and greater assistance with technological support from

509 UNIDO 2010, p. 85.

510 Chamas, Prickril & Sarnoff 2011, p. 81, with references and pointing to discussion elsewhere in Wong & Dutfield (eds.) 2011.

511 Cause for speculation is whether in the current economic slow-down in the "North", following the economic crisis, industry-protection will prevail over technology-transfer promises for a time to come. That would present more generally a danger to development perspectives in trade policies in the "North".

512 Compare Gollin, Hinze & Wong 2011, p. 359.

513 See extensively Drahos 2010, particularly pp. 285 ff.

developed countries. Developing countries should be allowed to exploit the TRIPS' flexibilities without trade-concerns, misinformation, or the imposition of external priorities. There is room within the globally standardized system for diversity with balancing of private and public interests.

After all, as the preamble to TRIPS states, the international IPR system should seek to "reduce distortions and impediments to international trade … taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade…"

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# PART II

## AGRICULTURAL SEEDS THAT REDUCE HUNGER AND POVERTY – POLICIES, PERCEPTIONS AND PRACTICES IN INTELLECTUAL PROPERTY RIGHTS

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## Contents

## EXECUTIVE SUMMARY

### *Goals and Objectives*

1. The Millennium Declaration contains a set of ambitious goals and targets that countries committed to, including under Goal 1 dealing with the eradication of extreme poverty and hunger, setting themselves a target to halve, between 1990 and 2015, the proportion of people who suffer from hunger (MDG 1c). Agriculture and particularly smallholder agriculture is central to meeting MDG 1c, and the use of good seed of adapted varieties is a major prerequisite for improving agriculture. Access by farmers to new varieties and access by breeders to the technologies and materials to develop them is central in this research, which aims to investigate the roles of Intellectual Property Rights (IPRs) in the management and sharing of knowledge for development.

2. We have studied the Intellectual Property Rights systems relevant to plant breeding (patents and Plant Breeder's Rights). We have taken the innovation chain approach, analysing the policies underlying the rights, perceptions and practices in applying the rights by stakeholders at funding organizations of fundamental and strategic research, research institutions and researchers in the Netherlands down to research for development funders and researchers in Africa (notably Uganda) down to smallholder farmers. The aim was to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries, and secondly to contribute to the realization of IP strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and which increase food security in developing countries.

3. The innovation chain can be read in terms of a "push", where technology is translated to products for farmers, but also as a "pull" starting from the end user. It addresses what are the needs of smallholders and how is their access to the different seed systems (see below) translated into breeding objectives and research programs.

4. The research involved interviews with a large number of stakeholders along this innovation chain, and the analysis of relevant policy documents, contracts, and literature. Uganda is selected as it represents a typical African least developed country which is highly dependent on agriculture. The Netherlands has a leading position in agricultural research and development, and has a thriving seed sector.

***IPRs may create obstacles at various points along the innovation chain:***

5. Since resource-poor farmers almost exclusively source new varieties from informal sectors, any IPR system that effectively disallows the informal sharing of seeds such as patents and some forms of Breeder's Rights will obstruct access to new protected varieties. Even though awareness of IPRs is generally low with public research directors in Africa, a broadly shared perception is that such rights, when applied to publicly bred varieties, could solve budgetary constraints of public research (including breeding), and

supplement low wages of breeders in the public service. Few realize the potential to tilt the focus of these institutions towards more commercially viable crops and farmers and away from poverty reduction goals. A low capacity to manage intellectual property in public research and breeding organizations either shies away potential foreign research partners from collaboration, or puts the African partner in a disadvantaged position in negotiations towards access of technologies. Such institutes furthermore operate in a policy environment where the framing of national IP policies is strongly influenced by international pressures, which makes it impossible for developing countries to balance the rights of inventors with those of their society. Ugandan institutions exercising IP-related mandates are quite disjointed or only coordinate with each other in an ad hoc manner, not contributing to tangible benefits to the country and its resource-poor farmers.

6. Dutch IP law and national innovation policies lack a specific development clause despite several international agreements that emphasize the responsibility of the industrialized countries to promote technology transfer to least-developed nations. There is no general IP policy at the ministries that finance agricultural research, and opinions diverge on the need for such a policy, while awareness among policymakers is low with respect to possibilities for IP to impede access to technologies in developing countries. International development policy and knowledge and innovation policy are organizationally divided and generally perceived as two worlds apart.

7. Some Dutch funding agencies and programs, however, have "valorisation" strategies, which is the basis for public-private partnerships in research. These strategies lack specific references to international development. Valorisation of research is commonly narrowly understood by such programs as the need to turn knowledge into (economic) value for the Dutch society - through IPR protection - and by universities, the acquisition of royalties of new research contracts. The involvement of the private sector in public research affects the conditions under which university IP can be accessed, and commonly leads to more exclusive arrangements.

8. Dutch public research organizations hardly include humanitarian licensing strategies in their research and IP contracts with (private) research partners, which could increase availability of technologies for development purposes. The perception is widespread that such humanitarian licenses can negatively affect the organization's own interest in the negotiations.

9. It is difficult and costly to secure freedom to operate for humanitarian projects given the IP landscape in agricultural biotechnology: Material Transfer Agreements (MTAs) often do not allow for product development; strategic patenting and restrictive licensing conditions are common; many IP laws only include a weak research exemption;n biosafety procedures for GM crops are very expensive and regulatory dossiers are held confidential. All these issues create restrictions for the sharing of technology in both industrialized and developing nations. A lack of research capacity in the developing country or the capacity to effectively deal with IP may be additional impediments to the use of potentially useful technologies for development.

***Policies and practices that are likely to ensure a positive role of IP in facilitating the development, transfer and access to agricultural innovations for smallholder farmers:***

10. This includes a recent recognition in several African countries of the informal seed system leading to a more careful balancing of rights and obligations in seed and Breeder's Rights regulation. International research agencies and some donors investing in agricultural research provide safeguards for access to new varieties by smallholders. Moreover, Plant Breeder's Rights may - when carefully framed and implemented - support the uptake of new varieties in the product portfolio of a seed enterprise, where otherwise the variety might be left 'on the shelf'.

11. In the Netherlands, there are some developments worth mentioning: An "Incentive Fund for Open Access Publications" has been established by the Netherlands Organization for Scientific Research (NWO); and there are some recent voices calling on the Dutch government to create more synergy between the organizationally divided worlds of international development policy and research and innovation policy. Finally, the Plant Sciences Group of Wageningen UR concluded an important humanitarian use license with a CGIAR partner and one in the US, which is a sign of a policy shift towards making technology more readily available for contributing to MDG1c.

12. Several solutions have been proposed in order to counteract the blocking effect of patents on the availability of genetic material for further breeding; and several humanitarian and open licensing tools have become available to secure and facilitate the accessibility or transfer of IP protected knowledge, materials and technologies for development purposes.

***We recommend that:***

13. If Uganda and other African countries are to support poverty reduction through research for development, they should formulate IPR laws that take into account the need for farmer-to-farmer technology transfer.

14. Public research organizations in Africa need to frame their institutional policies in such a way that both commercial and (near-) subsistence agriculture of the country can be supported. They need to increase their capacity in IP management in order to avoid concluding contracts that are not to the benefit of the country or the poorer constituency of farmers.

15. African countries should actively pursue the integrated seed system development pathway that recognizes the importance of farmers' seed systems next to the formal system.

16. Uganda should increase its policy coherence relevant to seeds and IPRs by making sure that the various institutions involved and their mandates are properly coordinated.

17. The Dutch government should create much more synergy between its research and innovation policy and its international development policy in the formulation of a general IP policy with respect to public research. This should involve an evaluation of the current research funding system and the development of criteria and incentive mechanisms for valorisation that go beyond mere economic outputs for the Dutch society and reach across borders. More expertise needs to be developed with respect to humanitarian licensing strategies at public research organizations and funding agencies.

18. The current patent system may need to be evaluated at the global level with respect to the need for a breeder's exemption in patent law, mechanisms to curtail strategic patenting, expanding possibilities for compulsory licenses, reducing the costs and inefficiency of the patent system, and the expansion of the "private and non-commercial use" exemption in Plant Breeder's Rights to all resource-poor farmers.

19. Obligations in international agreements to facilitate technology transfer for development purposes need to be actively pursued, and generic competition secured after termination of IP protection.

***Extending the outcomes to stakeholders and further research:***

20. The outcomes of the study will be communicated with the relevant stakeholders in Europe and Africa, starting with the various actors interviewed.

21. The outcomes will be included in curriculum on IPRs in the Life Sciences at Wageningen University, and invitations have been accepted to discuss them with the Uganda Seed Trade Association and the African Union Secretariat in Addis Ababa. They will also be discussed in the Network of IP-Professionals of the Central Advisory Service on IP of the CGIAR (the National Partners' Initiative) during its annual meeting – scheduled in South Africa in July 2011.

22. The project results will be included in international mid-career training programs of the Centre for Development Innovation in Chennai (2011) and Wageningen (2012). There is also an interest from a SIDA-funded training program on Genetic Resources and Intellectual Property Policy that will be held in Alnarp – Sweden, and (probably) in Nairobi, Kenya in 2011.

23. The results also warrant further research. They will be included in the work plan of a project sponsored by Netherlands Organisation for Scientific Research (NWO) on "Intellectual Property Regimes for Pro-poor innovation in agriculture" under its "Responsible Innovation" program, and other research proposals on the development of criteria and incentive mechanisms for valorisation of agricultural research across borders.

# CHAPTER 1 INTRODUCTION

*Niels Louwaars & Bram De Jonge*

## 1.1 Research Objectives

The adoption of the Millennium Development Goals (MDGs)[1] in 2000 was heralded as an important milestone in the global development discourse. Adopted at the United Nations Millennium Summit, the Millennium Declaration contains a set of ambitious goals and targets to which countries committed, setting themselves a deadline of 2015. Under Goal 1 dealing with the eradication of extreme poverty and hunger, countries set themselves a target to halve, between 1990 and 2015, the proportion of people who suffer from hunger (MDG 1c). However, the MDG Report 2009 indicated that most of Sub-Saharan Africa suffers from moderate to extremely alarming hunger and that, for the sub-region, the declining trends in hunger registered since 1990 were reversed in 2008 as the proportion of people going hungry increased.[2] Agriculture and particularly smallholder agriculture are central to the capacity of states and the international community to meet MDG 1c. However, a combination of adverse ecological conditions, diseases and pests, and the lack of access to appropriate technologies constitute some of the most important impediments to achieving improvements in agricultural productivity in most of Sub-Saharan Africa.

The lack of access to appropriate agricultural technologies in many developing countries is the main focus of this research project, which aims to investigate the impact of IPRs on the attainment of the MDGs. The central research question holds: *What is the role of IPRs in the management and sharing of knowledge for development?* This part of the report examines the relationship between IPRs, agriculture, and MDG 1c. For that purpose, we will analyse the roles that different IP policies and practices play in agricultural research and development trajectories in the developed and developing contexts. Ultimately, the aim is 1) to map the main obstacles and opportunities that IPRs create for the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries, and 2) to contribute to the realization of IP strategies and recommendations that improve the development and accessibility of agricultural inputs that are relevant for resource-poor farmers and that increase food security in developing countries.

## 1.2 Research Approach and Structure

In order to get an overview of what issues are at play, we focus on the main actors that directly or indirectly impact upon IP policies and practices in relation to agricultural research and technology transfer. Hereby, we focus particularly, but not exclusively, on two countries: one developed country – the Netherlands, and one Least Developed Country – Uganda. Uganda is selected because it not only represents a typical African least developed country but its economy and an estimated 85% of the rural population are dependent on agriculture.

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1 See <http://www.un.org/millenniumgoals/>(accessed on March 16, 2011).

2 UN 2009. Available at <http://www.un.org/millenniumgoals/pdf/MDG_Report_2009_ENG.pdf> (accessed on March 16, 2011).

The Netherlands, meanwhile, is a developed country that holds a leading position in agricultural research and development, and that has a thriving seed sector, particularly in potato, vegetable and ornamental crops.

Key players in the agricultural innovation chain are governmental organizations at various levels, funding agencies, research organizations, companies, and last but not least, farmers. Along this chain, we will analyse the IP regulations, policies, and practices that are implemented by the various actors and report on their experiences and perceptions with respect to the effects of IPRs on the development, transfer and availability of knowledge and technologies for the benefit of resource-poor farmers and the attainment of MGD 1c. Input for these analyses is derived from literature studies and semi-structured interviews with stakeholders. In addition, the relation between IPRs and pro-poor innovation is analysed in more detail on the basis of several case studies that focus on different crops.

In this *Chapter 1*, we will set the scene by introducing the key elements that form the basis of this research project. Starting with a reflection on MDG 1c, we will subsequently introduce the innovation chain and its various actors, the notion of formal and informal seed systems, and the Intellectual Property Rights (and some other rights) that are particularly relevant for the agricultural sector and biological research leading to improved seed.

The next three chapters focus on Uganda, with *Chapter 2* starting at the level of resource-poor farmers by investigating how Ugandan farmers access improved seed. The analysis of the ways that farmers acquire seeds and particular through which kind of ways new varieties reach the poorer and/or more commercial farmers is a basis for analysing the waysthat IPRs could affect seed related technology transfer. The chapter is based on case studies in Uganda on the important food security crops beans, cassava, maize and (Irish) potato.

*Chapter 3* examines the current trends in the development of IP regimes in Africa, the key influencing factors and how these regimes impact on agricultural R&D and access to new seed varieties by resource-poor farmers. By looking at the case study of Uganda, we analyse the formal policies at national and institutional levels and what the drivers are/have been to arrive at these.

*Chapter 4* then concentrates on the institutional policies of research organizations that develop new technologies for farmers in Africa, and their funders. This chapter takes a broader perspective than the case study of Uganda and is based on a significant number of interviews with research managers from various African countries. By analysing some research contracts, the chapter studies the impact of international agricultural research centres and funding partners on IP policies of the African agricultural research institutions.

*Chapters 5 and 6* deal with the Netherlands. *Chapter 5* focuses on the policy level. It analyzes how agricultural research is organized in the Netherlands, what IP laws and policies apply, and how these factors impact upon the room for pro-poor innovation. It analyzes coherence in public policy by studying different ministries, public funding agencies, national research programs, science associations, and (public) research organizations.

*Chapter 6* then deals with IPRs in practice, focusing on the experiences of public researchers, public IP managers, and industry representatives with accessing and transferring research materials. We study four research projects that aim specifically at transferring agricultural technologies to developing countries, and analyse the use and management of the IPRs involved and their positive/negative roles in reaching the project's objectives.

Finally, *Chapter 7* will sum up the main IP obstacles and best-practices that we encountered, and present our recommendations on IP policies and instruments that can be applied by different actors along the innovation chain in order to make IPRs work towards meeting MDG 1c. Lastly, we will list our ideas regarding the valorisation and follow-up of this research project.

### 1.3 MDG 1c

The Millennium Development Goal 1c sets an ambitious target of halving the number of people who suffer from hunger during the period 1990 to 2015. Production of food is one of the cornerstones of this MDG. A distinction has to be made here between coping with hunger in urban and in rural areas. For the former, food should be as cheap as possible; for the latter the only way out of poverty is to have a fair price for the surplus food that is produced by smallholder farmers. Linking smallholders to markets is considered key in fighting rural poverty and hunger.[3] Producing food where it is most needed is the strategy for fighting hunger and malnutrition and has been a basis of the concept of food sovereignty. Recent hikes in food prices in the global market have indeed shown governments that relying on cheap imports is not a good strategy. The same accounts for food security within a country: promoting market-oriented production by large-scale farmers is an important strategy for national food security in developing agricultural economies. But for improving household food security and reducing hunger and malnutrition in rural areas, also improved production by rural smallholder farmers is necessary. Where increasing the yield potential and closing the yield gap are imperative in commercial production systems, smallholder farmers also prioritize yield stability as a key challenge, notably in situations of climate change.

Technology is important for farmers to improve their situation or even to cope with changing conditions such as climate change, decreasing soil fertility and reduction of farm sizes in many developing countries. Seed is an important carrier of technology that enables farmers to meet their pressing needs. The quality of seed determines the germination and health of the emerging crop and thus provides the yield potential; the genetic information embedded in seed, furthermore, provides the opportunities for the crop to withstand abiotic (e.g., drought, heat) and biotic (insects, diseases) stresses and it determines to a large extent the culinary and nutritional qualities of the harvested product. Seed – in combination with other agronomic improvements – has proven to be responsible for major transitions in agriculture both in industrialized and developing countries. A distinction has to be made, though, between "seed" as an input for any crop production - with its important features "quality" and "availability" - and "variety", which is the kind of seed, determined by the genetic build-up, and transferred from one generation to the next. Seed is the tangible and variety the intangible carrier of technology in crop production.

Opposite to inputs like fertilizers and pesticides, where inputs are bought on the basis of the needs per hectare, is improvement of varieties, which have since the start of the Green Revolution been considered scale-neutral, as a small investment in seed could bring large and lasting benefits for farmers. However, two major insights put questions to this widespread idea:

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[3] World Bank 2007. Available at <http://publications.worldbank.org/index.php? main page=product_ info&products _ id=22727> (accessed on March 16, 2011).

1) Crop improvement is in many cases directed to particular agro-ecologies, and improved varieties do better in the ecologies for which they have been selected and may even perform worse than the local materials in other situations.[4] Investment in breeding, both in the public and private sectors, needs to go to the largest 'recommendation domains'.[5] This means that breeding is much easier for uniform and ecologically benign conditions, and that variety development for resource-poor farmers in ecologically diverse areas is difficult.
2) When the technology embedded in seed has to be purchased every season (like with hybrids or under some intellectual property regimes), seed becomes as scale dependent as fertilizer.

This case study intends to contribute to MDG 1, target 1c by investigating the effects of different types of Intellectual Property Rights systems on the delivery of technology (embedded in the variety and delivered through seed) to resource-poor farmers in developing countries. We use a chain approach to analyse the flow of technology from high-tech innovation - in our case in the Netherlands - through a number of steps until it may reach resource-poor farmers in Africa, using Uganda as a typical example of an African least developed country.

### 1.4 The Innovation Chain

The chain from technology development (e.g., using molecular biology), through variety development (plant breeding), and seed production and distribution, is long and diverse. Different agents – researchers, breeders, seed technologists, businessmen – are involved and all have their specific environment that they work in. Funding is – parallel to profit expectations in the private sector - an increasingly important driver for providing direction of upstream public sector research, and for the research partnerships that are built. These in turn greatly affect the chance of the research products reaching – or being relevant for – resource-poor farmers. It is therefore important to identify to what extent, or if at all, MDG 1c is taken into account in such research funding policies.

Furthermore, public agricultural research institutions in both industrialized and developing countries have their own strategies in choosing the direction of research and in making available their products – in this case varieties or improved materials that commercial breeders can use to further develop varieties. These are based on their own mission and vision, which are affected by their sponsors. It is thus important to see how MDG 1c is reflected in such mission and vision and how these are translated into action.

Of particular interest is how the variety is translated into a usable product that can perform the promised transition: the seed. Who will multiply and distribute the seed and how may such seed reach the particular focus of this study – the smallholder farmer. This requires an analysis of the seed systems in the developing countries and the regulations that guide them.

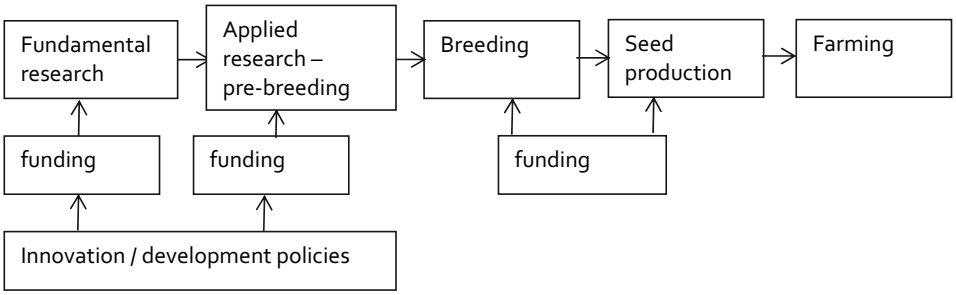
Intellectual Property Rights play a role in all these components – in public research policies and research partnerships, in expectations for financial revenue, and in downstream

4 Ceccarelli 1994.

5 Chambers, Pacey and Thrupp 1989.

arrangements between breeders and seed producers. Research on the impact of IP on technology for smallholder rural farmers thus needs to take into account the whole innovation chain where public, private and civil society partners play their respective roles.

***Figure 1.1: The innovation chain in Agriculture***




The innovation chain can be read in terms of a "push" where technology is translated into products for farmers, but also as a "pull" starting from the end user: how are the needs of smallholders and their access to the different seed systems (see below) translated into research programs and breeding objectives. Or – how are policies to increase agricultural productivity and reduce hunger translated into action with regard to seed-related research and development in both developing and industrialized countries? In the organization of this case study we take the latter approach. The smallholder rural farmer is the starting point of the analysis (Chapter 2).

## 1.5 Seed Systems: Formal – Informal

We know that for different crops, seed systems operate – even in the same country – in rather different ways. Seed has since the dawn of agriculture been produced by farmers themselves. In that process, they domesticated plant species and selected them to serve their crop production and consumption needs. The saving and selection of seed on-farm and the sharing of seed among neighbours and kin is called the *informal*, traditional,[6] local[7] or farmers' seed system.[8] Only in the 19th century, specialized seed production emerged in Europe and the US, and only since the rediscovery of Mendel's laws of heredity in 1900 scientific plant breeding started. In the 1970s, advances in molecular biology started to affect plant breeding, leading to a range of biotechnologies that can be used in breeding. Such seed provision by specialized actors, who are commonly regulated by government and industry rules, is dubbed the *formal* seed system.

Government involvement in seed systems originates from the late 19th century in Europe when farmers called for independent quality controls of seed (and varieties) in the market.[9] Seed quality and availability became not only a worry for each farmer, but also – within the framework of food security and rural development policies – a focus of government policies.

6 Cromwell 1996.

7 Louwaars & van Marrewijk 1996.

8 Almekinders & Louwaars 1999.

9 Louwaars & Burgaud in press.

Public plant breeding research started in European countries in the early 20th century and was soon after introduced in their colonies, where investments were initially geared to cash crops like cotton and coffee. These initiatives formed the basis for public food and crop research institutes at the national level and – since the late 1950s - the international level. In this respect, agriculture is unique in that it has attracted significant public investment in research and development. With the development of a private seed sector, such investment went upstream towards more fundamental research in industrialized countries for most crops (in the Netherlands today only varieties of fruits such as the 'Elstar' apple, and small industrial crops, are bred by the public sector).

The fact that farmers can in principle reproduce their own seed is critical in the analysis of seed systems. In most developing countries, less than 10% of all the seed that farmers use is produced by specialized producers; the remainder is produced by farmers themselves or sourced locally (neighbours, relatives, and local grain markets). Also in most of southern Europe, these informal systems are predominant for major food crops.

In many developing countries, governments have invested in producing seed in order to boost national agricultural production. Since the structural adjustment strategies in the 1980s,[10] policy is to stimulate private sector involvement. However, in most developing countries, this is limited to crops where competition from farm-saved seed is less (e.g., hybrid maize and vegetables) and to farmers that can afford a good price for good seed. The importance of formal and informal system depends largely on:[11]

- the breeding method of the crop: self-fertilizing crops can easily be multiplied on-farm,
- the multiplication factor: for some crops, over 10% of the physical harvest has to be invested in the seed – e.g., groundnut - for others less than 1% - e.g., maize,
- the use of the crop: for marketed crops, smallholders commonly have some cash available for inputs such as seed and for mainly home consumed crops such cash and thus opportunities to purchase seed of new varieties is commonly lacking,
- Government policies.

Formal seed systems are organized and regulated through seed laws. These prescribe how the identity and purity of the seed has to be guaranteed (certification), how the physical qualities are to be tested and the minimum standards that have to be met. A certification system identifies different classes of seed in order to maintain the genetic qualities from the small amounts of seed that a breeder maintains to the quantities that farmers need. New varieties are tested for their 'value for cultivation and use' (VCU) in both Europe and most developing countries before they can be marketed. These rules protect farmers from using substandard seed and provide a level playing field for competing seed companies. Even though according to the letter of the law in many countries these rules also apply to informally exchanged or sold seed,[12] they are hardly ever implemented since they are not being policed in most situations. The rules and the effectiveness of their implementation have a significant effect on the operation of the formal seed sectors.

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10 Policies by the international Monetary Fund and the World Bank that made loans to developing countries subject to reduced public expenditure.

11 Almekinders & Louwaars 1999.

12 Louwaars 2005. Available at <http://www.grain.org/seedling_files/seed-05-07-2.pdf> (accessed on March 16, 2011).

In developing countries, the formal seed systems are very weak or non-existent for most food crops (cereals other than maize, most pulses and root crops like cassava) and do not easily reach resource-poor farmers with seed. Governments continue to invest in breeding of such crops, and researchers try to find ways to reach smallholders with varieties through alternative mechanisms such as participatory variety selection.[13]

Next to an indispensible input for agricultural production, seed is also a valuable commodity. In the Netherlands, the seed sector (including vegetative planting materials) is thriving. It has been responsible for a steadily increasing export value of seeds and planting materials over the last 20 years rising to an estimated € 2.5 billion, and involving a labour force of approximately 10 000.[14] The most important sector is horticulture: all top ten vegetable seed companies have their main office or an important research establishment in the Netherlands. The Netherlands is the global market leader in the development of new potato varieties and the export of certified seed potatoes, which amounts to some 700 000 tons a year.[15] It is therefore not an accident that the Netherlands is increasing its focus on seeds in its development policy.[16]

### 1.6 Intellectual Property Rights in Seeds

IPRs aim at stimulating innovation by providing a market incentive through exclusive rights. The patent system has not been applied for long in the seed sector because of ethical, legal, technical and food security reasons.[17] Separate, so-called '*sui generis*' systems emerged to support private investments in the sector. The US introduced a separate amendment to the patent law in 1930 to provide protection for some vegetatively propagated crops and in various European countries Plant Breeder's Rights (PBR) systems emerged soon after.

#### 1.6.1. Plant Breeder Rights

Plant Breeder's Rights systems were harmonized from 1961 onwards in the Convention on the Protection of New Varieties of Plants, and supported by the Union for the Protection of New Varieties of Plants (UPOV)[18] as the secretariat. They combine protection of the end product (the variety) while maintaining the agricultural tradition of exchange of materials and saving of seed by farmers –i.e., the *farmers' privilege*. By protecting only the end product (the variety) and by keeping these freely available for anybody for further breeding – i.e., the *breeder's exemption*, PBR systems have a strong open source character compared to patents. The right of farmers to save seed has been gradually restricted over the past 50 years in subsequent Acts of the UPOV Convention. In the latest Act of 1991, developed in response to the changes in agriculture in the then – developed country – members of the Union, countries may identify crops and conditions for which this applies, and the use of the saved seed is explicitly

13 Almekinders & Hardon 2007.

14 TTI GG 2007. Available at <http://www.groenegenetica.nl/pro1/ general/start.asp?i=0&j= 0&k= 0&p=0&itemid=71> (accessed on March 16, 2011).

15 See FAOSTAT. Available at <http://www.potato2008.org/en/world/europe.html> (accessed on March 16, 2011).

16 WRR 2010.

17 Louwaars 2007.

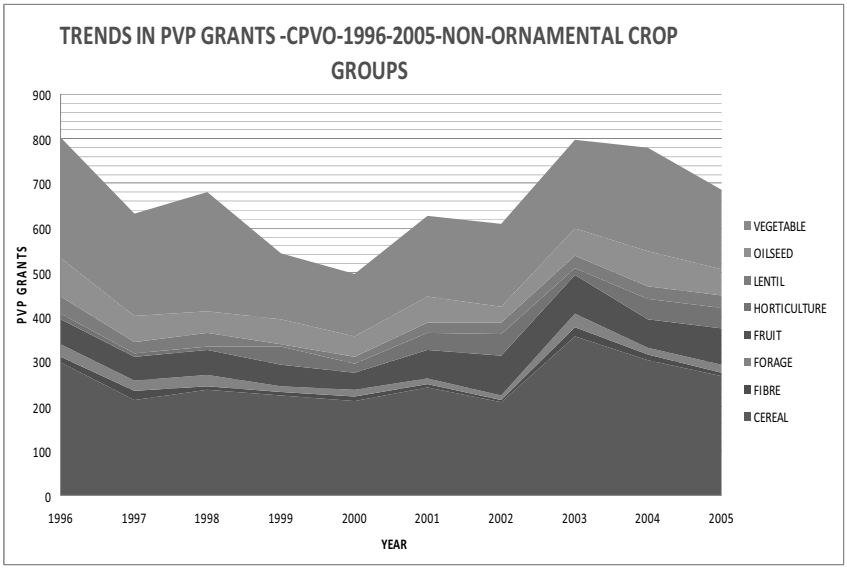
18 See <www.upov.int> (accessed on March 16, 2011).

restricted to the farmers' own holding. Thus, exchanging seed of protected varieties is not allowed anymore since this falls within the scope of the breeder's right.

The existence of such special protection systems for plant varieties was reflected in the TRIPS Agreement of the WTO,[19] which includes special provisions – in Article 27(3)b - for plant varieties. Countries may exempt plants and animals from patent protection, but when they do they should "provide for the protection of plant varieties either by patents, or an effective *sui generis* system or any combination thereof".[20] Many developing countries choose for the *sui generis* option – and some have become members of UPOV. Most countries follow the European example to exempt varieties from patentability. However the USA promotes the patent system in most of its bilateral trade negotiations.

The number of new Plant Breeder Rights[21] certificates issued by the Community Variety Protection Office of the European Union is some 2000 per year, mainly for ornamentals and some 700 for all other crops (fig 1.12).[22] Yet, it should be noted that for many vegetable crops no Breeder's Rights are applied for because of the hybrid nature of the varieties and because the economic lifetime of a new variety is often relatively short (3 to 5 years) due to on-going improvements.

***Figure 1.2: PBRs for non-ornamental crops in the EU (CPVO), 1996-2005.[23]***




19 See http://www.wto.org/english/tratop_e/trips_e/trips_e.htm (accessed on March 16, 2011); See PART I.

20 TRIPs 1995, Article 27(3)b.

21 Also referred to as Plant Variety Protection (PVP) or Plant Variety Rights (PVR).

22 Louwaars et al. 2009. The number of PBRs for ornamental crops is much higher, constituting about half of all PBR applications to the CPVO in 2008.

23 Idem, p. 31.

### 1.6.2 Patents

The patent system became relevant in the seed sector following court cases on the protection of biotechnological inventions in the US in the 1980s (see Box II-1) and the 'Biotechnology Directive' of the European Commission (98/44/EC) in 1998.[24] The number of patents in the field of plant breeding has rapidly increased, and together with technological developments and general globalization trends triggered a significant concentration in the global seed industry. A recent study reports that a total of 4.048 EPO patent applications relevant to plant breeding were submitted between 1980 and 2006. In the US, 5.506 patents were granted between 1980 and 2006, and 5.070 new ones applied for between 2001 and 2007 only (patent application data became available in 2001 only). Relevant patents are very much concentrated in the hands of a few multinational companies, with the top five patent applicants in Europe submitting 31.4% of all applications in the period 2000-2004, and even 71.7% in the US in the period 2003-2007.[25]

**Box II-1: Developments in the Patentability of Plants: Extension of Rights in the US**

- *Diamond vs. Chakrabarty* (1980)[26] involved the first patent on a man-made micro organism
- In 1985, plants were considered patentable following the ruling in *Ex parte Hibberd*.[27]
- *J.E.M. AG Supply, Inc. vs. Pioneer HiBred International, Inc.*,[28] made plant varieties protectable by utility patents independent of rights under either the Plant Patent Act of 1930 or the Plant Variety Protection Act of 1970.

The public research sector (including universities, governmental agencies, and private non-profit organizations) plays a significant role with some 25% of plant-based patent applications (fig 1.2),[29] which is considerably more than the 2.7% over all sectors.[30] The rate is however decreasing sharply of late in the US, likely because of changes in institutional policies following reports that only very few universities gain a net profit from the management of their protected intellectual assets. In Europe, this fall in the share of the public sector is much lower.

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24 See PART I.

25 Louwaars et al. 2009, pp. 34-36. The top five applicants in the EU and US, although in different order, are Pioneer Hi-Bred, Monsanto, Syngenta, BASF and Bayer CropSciences.

26 *Diamond vs. Chakrabarty* 1980.

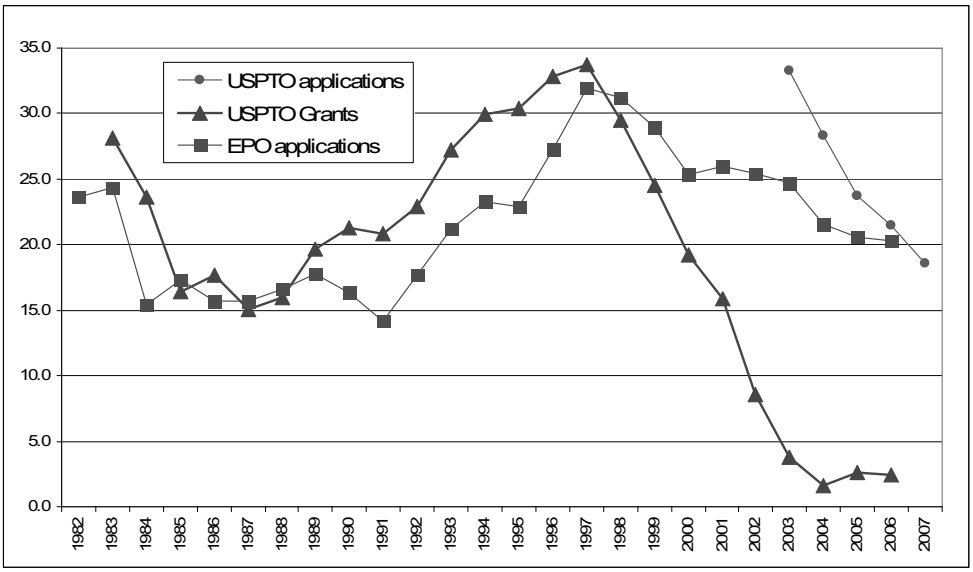
27 *Ex parte Hibberd* 1985.

28 *J.E.M. Ag Supply vs. Pioneer HiBred* 2001.

29 Louwaars et al. 2009, pp. 36-37.

30 Graff et al. 2003, p. 990.

***Figure 1.3: Share of the public sector in applied and granted plant-based patents (in %).***[31]




The strengthening of Intellectual Property Rightson plants indicates a gradual shift in the balance of power from farmers to breeders following the reduction of the farmers' privilege in Plant Breeder's Rights and from breeders to biotechnologists following the evolving patent system. A response is currently visible with some downward trend on the patentability of life science technologies in the US and Europe following recent court cases (see Box II-2), a more stringent approach by the European Patent Office under the title 'raising the bar', and debates in Europe to change the patent system to reduce the impact of biotechnology patents in the sector by various forms of breeders' exemptions in patent laws. African countries generally exclude plants and plant varieties from patent protection, following policies agreed upon at the level of the African Union.[32]

**Box II-2:** ***Developments in the Patentability of Plants: Recent Reduction of Patentability***

*A recent trend in case law in the US indicates that the applicability of the patent system in agriculture is reduced to some extent. Patents on expressed sequence tags (ESTs) have not been accepted since 2005 because of insufficient proof of 'industrial application' and the publication requirements (In Re Fisher).*[33] *Recent rulings on patents on (human) genes indicate further restrictions based on a perceived lack of inventiveness (In Re Kubin and Goodwin)*[34] *and novelty (Association for Molecular Pathology et al. vs. U.S. Patent and Trademark Office et al.).*[35] *The United States Patent and Trademark Office (USPTO) will respond to these rulings with a more restrictive policy towards granting patents on plant traits.*

31 Louwaars et al, 2009. p. 37.

32 Louwaars *et al.* 2006.

33 Re Fisher 2005.

34 Re Kubin and Goodwin 2009.

35 *Association for Molecular Pathology et al. vs. U.S. Patent and Trademark Office et al.* 2010.

*In Europe, recent decisions are also curtailing patents on plants to some extent. The European Court of Justice ruled in July 2010 (In* Monsanto Technology LLC vs. Cefetra BV and Others*)[36] that Monsanto cannot claim rights on soybean meal imported into Europe grown from soybean seeds that are reproduced without the consent of Monsanto in Argentina (where the company does not hold a patent on the Roundup Ready technology).It ruled that under the Biotechnology Directive genetic material can be protected only when it is performing its function, and that because the DNA sequences in the imported soy meal are considered "dead material" no longer performing their function, they were no longer protectable pursuant to Article 9 of the Directive.*

*In an appeal by Limagrain and Syngenta before the Enlarged Board of Appeal of the European Patent office against a patent on a breeding method for broccoli, the board decided in December 2010 that the methods are to be considered essentially biological and thus not patentable.[37]*

IPRs aim at stimulating innovation by providing a market incentive through the exclusive rights attached. However, how IPRs affect predominantly non-market actors, such as food insecure smallholder farmers, is unclear. Could IPRs stimulate the development of varieties specifically adapted to smallholder conditions, and could they support the development of more effective distribution mechanisms of improved seed materials to near-subsistence farmers? Or could they steer research priorities in the public sector away to more profitable crops and markets? And what are the consequences of the growing role of patents in the biotechnology sector for research partnerships between industrialized and least developed countries? These are just a few questions that relate to the overall research question of the project about the roles of IPRs in agriculture and meeting the target of halving the proportion of hungry people by 2015 as set out in MDG 1c.

### 1.7 Other Rights

Apart from patents and Plant Breeder's Rights, some other rights are important in the agricultural sector. These are other Intellectual Property Rights, and rights arising from biodiversity law, and market/contract regulations.

#### 1.7.1 Other IPRs

In the commercial seed sector, similar to all other businesses, trademarks are of vital importance to protect a company's reputation and thus the value of its products in the market. Seed producers in developing countries have indicated that in an emerging seed market, trademarks are at least as important as other IPRs.[38] In few cases, Geographical Indications may – when connected to particular local varieties – provide some protection as well. In advanced plant breeding, trade secrets are gaining importance. This is particularly the case in protecting the parent lines of commercial hybrids. There is also an increasing tendency to protect parent lines through PVP.

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36 *Monsanto Technology LLC vs. Cefetra BV and Others* 2010.

37 See <http://documents.epo.org/projects/babylon/eponet.nsf/0/E72204692CFE1DC3C12577F4004BEA42/$File/G1_08_en.pdf> (accessed on March 16, 2011).

38 World Bank 2006.

### 1.7.2 Rights on Biodiversity and Traditional Knowledge

National laws based on international agreements on biodiversity are being developed in an increasing number of African countries. Such laws regulate access and use of genetic resources, the building blocks of plant breeding, both in terms of international exchange and with regard to the use of farmers' varieties as parents in breeding programs. The Convention on Biological Diversity (CBD)[39] formalized national sovereign rights over (plant) genetic resources and allowed countries to make access to such resources subject to "Prior Informed Consent" and "Mutually Agreed Terms". It also assigns rights to local and indigenous communities on their biodiversity and related traditional knowledge. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[40] furthermore includes Farmers' Rights, including the right of farmers to:

- protect their traditional knowledge relevant to PGRFA
- share in the benefits arising out of the use of PGRFA
- participate in decision-making at the national level relevant to PGRFA
- save, exchange and sell farm-saved seed (subject to national law)

Such rights affect the access to genetic resources and their use by plant breeders and farmers, and may create some confusion with regard to the operation of the patent and breeder's rights.[41]

In November, the Nagoya Protocol was concluded by the Conference of Parties of the CBD[42]. This protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their use provides an important step towards globally agreed norms. For the purpose of this report it is particularly important to note that agreements for particular components of biological diversity can be made, and that the international treaty is explicitly mentioned in the Protocol.

### 1.7.3 Market Regulations

A number of market regulations also affect the use of seeds and/or agricultural technologies in a variety of ways:

- Seed certification
  Seed certification regulations aim at guaranteeing seed quality. They regulate a generation system starting with small amounts of very pure breeder's seed that are the basis of each multiplication cycle. Access to such breeder's seed creates some opportunities for the breeder to exclude parties from producing certified seed. This can thus be considered a non-IP exclusive right.

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39 CBD 1992.

40 ITPGRFA 2001.

41 Louwaars 2007.

43 Involves production of high quality seeds of improved varieties in a seed program and this may include commercial companies, parastatals, regulatory agencies and registered cooperatives. The seed program is involved in plant breeding and development of varieties, controlled seed multiplication, careful seed processing and packaging, seed quality control and certification.

- Biosafety laws
  National biosafety laws – based on the Cartagena Protocol of the CBD – require parties who introduce a genetically modified crop to provide evidence of the environmental and food and feed safety of their products. In most countries, these biosafety dossiers are proprietary and confidential. Even though breeders may use these plants for further breeding under plant breeder's rights, they may not be able to market their new (GM) varieties without negotiating access to the biosafety dossier – leading to non-IP exclusive rights again. The alternative would be to do the whole biosafety research all over again, which is extremely costly.

- Contract law
  Finally, the role of contract law should not be underestimated. Intellectual Property Rights are implemented by the holder through research and /or license contracts. Depending on the contract law, they are free to agree on any clause affecting research with and commercialization of the protected subject matter. When technologies are accessed by a research institute under a contract with the provider, they are commonly not allowed to transfer it to third parties, which might affect collaboration with developing countries. When developing country research institutes want to access proprietary technology, they may enter into a contract with a foreign technology provider even if the technology itself is not protected in their country, for example if the patent holder did not claim protection in the developing country or if the national patent authorities did not grant the application. In such cases, the signatory parties to the contract are bound by the agreement. Contract law determines what kinds of clauses are permissible, and thus what the reach of the agreement in the innovation chain may be.

# Chapter 2 Seed systems - How farmers access new varieties

*Julian Barungi & Godber Tumushabe*

**Abstract**
Intellectual Property Rights are a mechanism to promote and guide innovation. Whether such innovations in the life sciences reach farmers – and particularly resource-poor farmers who depend on their production for their livelihood and food security - is a key issue in assessing the role of IPRs in reaching the Millennium Development Goals**.** This chapter therefore assesses the ways that new varieties of some key food security crops reach farmers in Uganda. This is the basis for an initial analysis of the likely impact of IPRs on access to new varieties by smallholders, and of the key features of the IPR systems affecting such access.
For the crops studied – beans, cassava, maize, potato – it is clear that the informal saving and farmer-to-farmer exchange of seed is by far the most important source of seed for all farmers, and even more so for poor farmers in Uganda. This finding is supported by experiences from elsewhere. Both formal mechanisms[43] and a range of informal mechanisms[44] exist to channel the results of plant breeding to farmers. For maize, and particularly for hybrid maize, a commercial seed sector is thriving. Limited quantities of certified seed of the other crops are produced, mainly for sale to relief agencies. IPRs that disallow the saving of seed (e.g., patents) or that disallow the exchange of seed among farmers (patents and some forms of breeder's rights) could – if effectively implemented – severely disrupt seed security among smallholders. IPRs may on the other hand support public breeding for commercial farmers, and the further development of a private sector in crops that are reproduced for the market. These findings may guide the re-design of IPRs policies in the near future.

## 2.1 Introduction

In order to identify actual and potential effects of IPRs on access to technology in the form of improved seed varieties, it is important to find out the ways through which farmers access seeds. In this area it is important to analyse the pull factor – how do farmers obtain seeds and particularly how do they obtain seeds of new varieties – and the push factor – how do breeders reach farmers with their new products, which institutional arrangements are there to multiply and distribute the seeds and planting materials, and which farmers do these arrangements reach. Different crops have widely differing characteristics for both the pull and the push arrangements. Therefore, two vegetatively propagated and two seed propagated crops have been identified.

* Potato is a high value crop which is produced by many farmers mainly for the market. It is multiplied through seed tubers, i.e., basically the same product that is consumed. Farmers are thus able to reproduce their seed potatoes on-farm that, however, may carry a range of diseases that are difficult to control by smallholders.

[44] Involves selecting and saving seeds for sowing from the previous crop harvest. There is no defined technique in seed preparation and seed is not tested before planting. For more details, see Srivastara and Simarski 1986.

* Cassava is a basic food crop with high potential for other uses. The crop is easily multiplied through stem cuttings on-farm. Few diseases and pests may spread through these cuttings.
* Maize is a basic food crop in most of the country with a well-established grain market where surplus harvests find their ways to the cities. It is a cross-pollinated, seed-multiplied crop for which both open-pollinated and hybrid varieties are available. Hybrid varieties change the performance in terms of crop uniformity and yield potential when multiplied on-farm, hence farmers using hybrid seeds therefore generally purchase seed for every planting.
* Beans are a self-pollinated crop, for which the varietal characteristics do not change after repeated multiplication. Farmers are thus able to reproduce their seed on farm.

These four cases cover a variety of issues with regard to seed systems. The following introduces the four case crops in Uganda. The characteristics of the crop are introduced in the ways that breeders attempt to reach farmers (the push factor) and the ways that farmers access seed (the pull factor). This provides the basis for an analysis of the roles of IPRs in reaching farmers, particularly poor farmers that are targeted in MDG 1c.

## 2.2 Potato

### 2.2.1 Introduction

Potato is an important cash and subsistence crop in the highlands of Southwestern Uganda and in other highland areas in Africa. The potato crop is believed to have been introduced into Uganda around the 1900s mainly as a garden vegetable.[45] Potatoes are grown throughout the country, but their production is concentrated in the highlands (i.e., 1700-2500m above sea level) of Kigezi and Bugisu, where the incidences of late blight is less.[46] These are densely populated areas, and most potato growing is on small plots.[47] A number of diseases such as 'Bacterial Wilt' (*Pseudomonas solanacearum*), 'Early Blight' (*Alternaria solani*), 'Cercospora Leaf Spot' (*Cercospora* spp.) and several viral diseases greatly reduce potato yields. Despite significant work to identify resistant clones, the incidence of 'Late Blight' (*Phytophthora infestans*) is the most serious factor limiting potato production in Uganda. Production figures differ widely per source: Adipala et al. (2000) estimate a national production of 443,000 tonnes with yields averaging 7 t/ha, while the National Agricultural Research Organisation (NARO) estimates in 2001 1.2 million tonnes from 80,000 ha (yield 15 T/ha), which is closer to the average of 12.4 t/ha for developing countries.[48]

The growing demand for potatoes led to rising imports, and prompted the formation of the Kigezi Development Scheme in 1966 by the Department of Agriculture. Potato breeding was initiated at Makerere University in 1968 and started collaboration with the International Potato Center (CIP) in the 1970s. Currently, most potato research is done at Kalengyere Research Station (Kabale District) under NARO, which supplies less than 0.5% of the total seed potato demand. This means that on-farm seed saving is predominant; figures about seed exchange among farmers are not available, but are most likely substantial, implying that

45 Ministry of Agriculture and Forestry, 1981, p. 1.

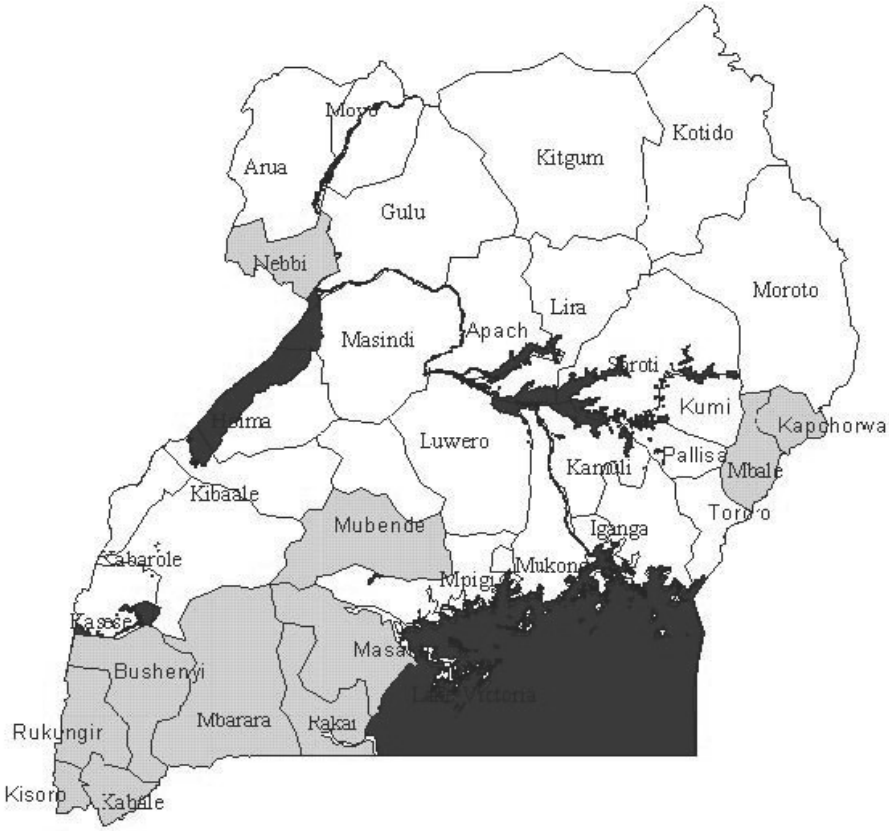
46 <http://www.betuco.be/Potato/Information%20on%20Potato%20Production%20in%20Uganda_.pdf, p.2.> (accessed on 1 July 2011).

47 For a detailed description of the potato sector in Uganda, see Ferris *et al.* 2001, p. 5.

48 Hakiza *et al.*, 1997, 2000.

this is the predominant alley for the introduction of new varieties to farmers that are not connected to the formal seed system.

***Figure 2.1: Potato producing districts in Uganda***




*Source: Ferris et al. 2001, p. 4.*

### 2.2.2. Supply Driven Access to Potato Seeds - Formal System

In Uganda, NARO is the sole source of disease-free starter seed potatoes[49]. The seed potatoes generated by NARO are availed to seed potato growers associations such as the Uganda National Seed Potato Producers Association (UNSPPA), Kapchorwa Seed Potato Producers Association and Buginyanya and Masira Cooperative Farmers' Association, who multiply the seed one more time and sell the product as "improved seed potato" to ware potato[50] growers. The basic seed potato is also availed to NGOs working with farmers in various districts such as Africare in Kabale and AT, Uganda in Kapchorwa as well as farmer

[49] Seed used for starting plants.

[50] Grown for food and not seed.

groups facilitated through various government programs like National Agricultural Advisory Services. UNSPPA has a self-policing quality control system and it multiplies a significant proportion of the starter seed potato available. The remainder of the seed potato is distributed through NGOs to farmer groups, or is bought by individual seed potato multipliers[51]. This approach to multiplying starter seed is highly informal but is supported by research organizations (NARO and ASARECA) and development organizations (USAID and CIP), which provide technical backstopping through the supply of disease-free elite seed (basic seed potato from Kalengyere research station), and through training services in potato pest and disease management, crop and nutrient management, and farming as a business.[52]

UNSPPA was formed in 1999 by farmers from Nyabyumba potato group in Kabale. The group was formed in 1998 by farmers with the support of Africare, an international NGO, as a farmer field school focusing on production of ware potatoes (fig 2.2). However, the yields were low because of the poor quality of the local seed potato stocks, hence the group's diversion of focus to production of disease-free seed potato with support from PRAPACE and NARO. Within the first 3-4 years of existence, the association successfully produced seed potato as shown in figure 2.2 before the demand for seed potato suddenly declined as the local NGOs had supplied enough seed potatoes to their clients. This is indicative of potential conflict between seed provided for free by NGOs and seed sold by commercial seed growers.

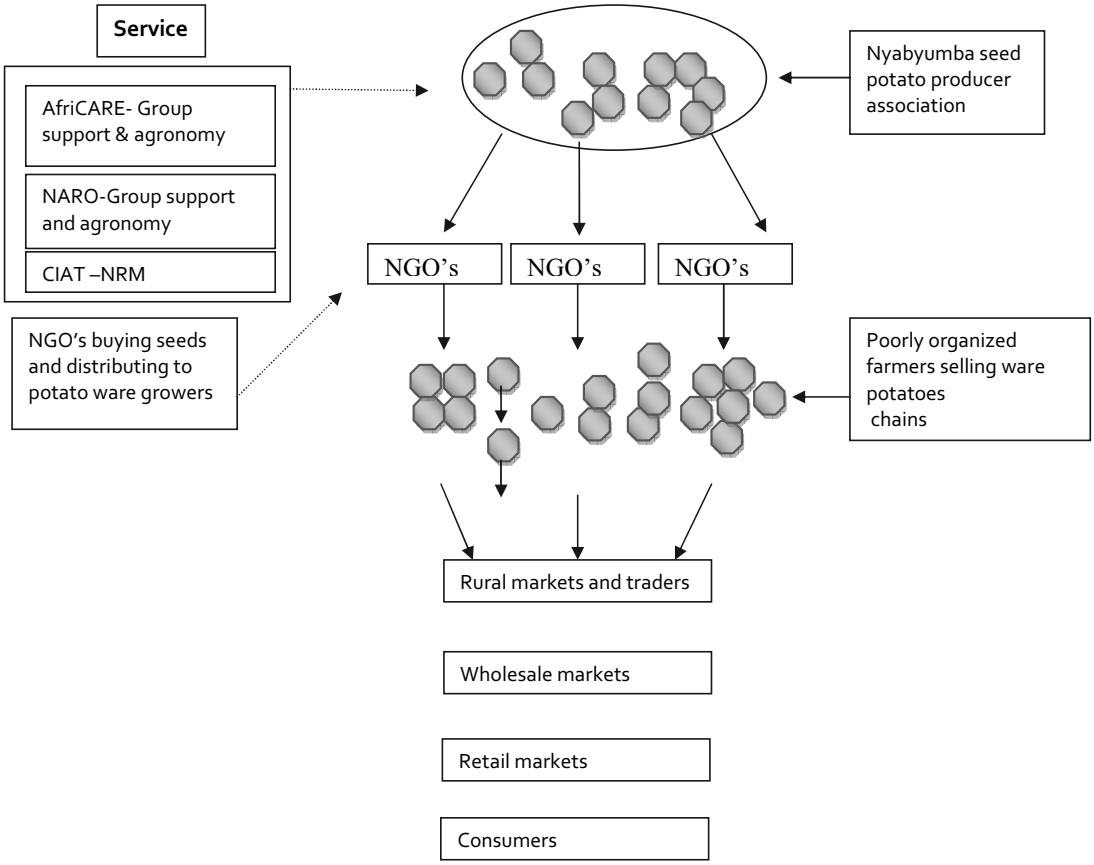
Figure 2.3 illustrates the new marketing strategy developed by the International Centre for Tropical Agriculture (CIAT) to sell off farmers' increased volumes of ware potatoes that had been achieved as a result of the good quality seed potato. It generally shows the original channel by the association where seed potatoes were mainly sold to NGOs in Kabale district who then supplied them to farmers at no cost. Figure 2.3 shows a fairly upgraded channel developed by CIAT which worked with other service providers (their services are shown in the same figure like PRAPACE, Africare and NARO to test CIAT's participatory approach for agro-enterprise development that combined the supply of seed and ware potato in an entrepreneurial fashion. The farmers decided to concentrate on supplying Nandos, a multinational fast food restaurant in Uganda. In this more formalized approach, the quality and supply parameters were more stringent compared to the informal market (Figure 2.2) requirements. So in order to offset the risk, farmers identified alternative markets. For example, these farmers sold potatoes that had not met Nandos standards or those that would be rejected by Nandos' target market, to wholesale markets in Kampala.[53]

[51] For more details, see Wagoire *et al.* 2005, p. 741.

[52] See AT Uganda Ltd 2005, p. 103.

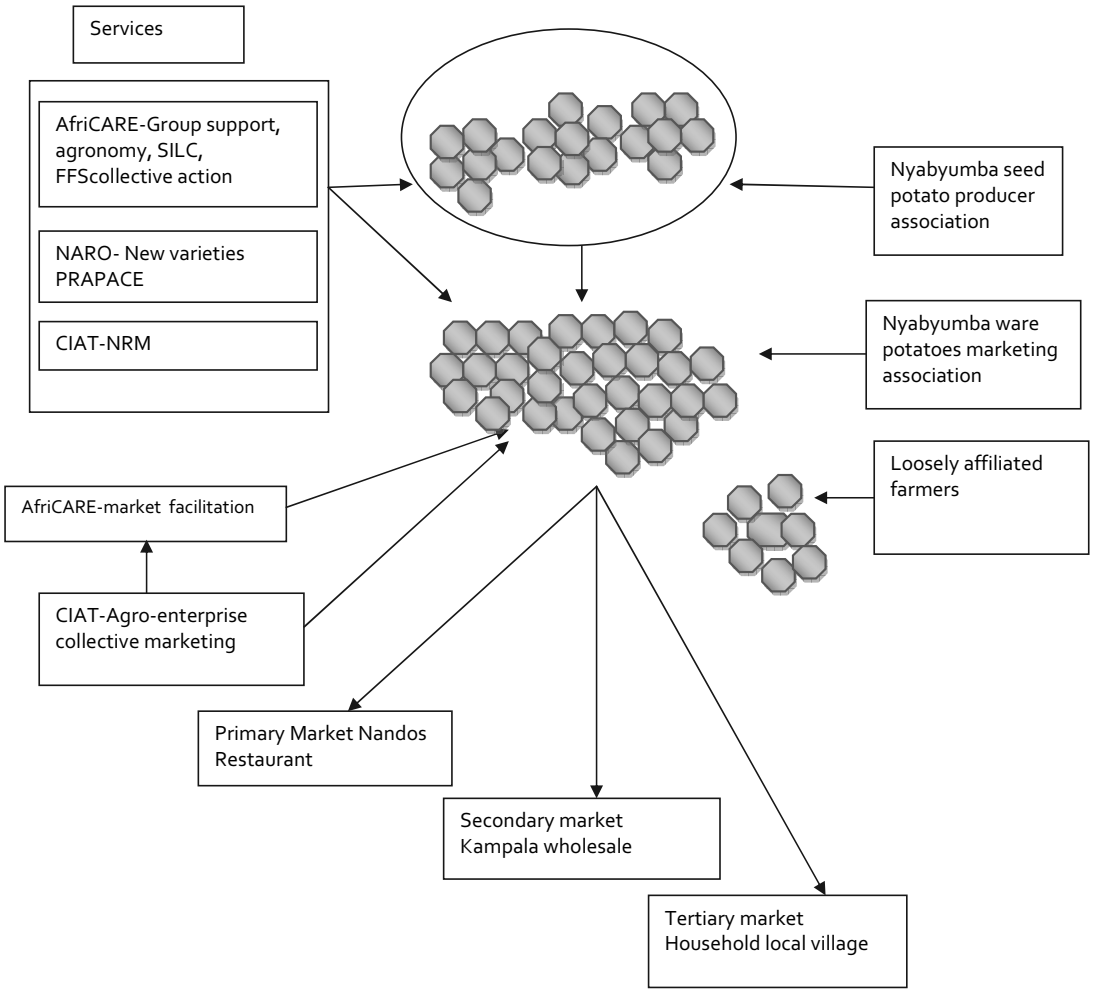
[53] See CAPRi 2008.

***Figure 2.2: Informal seed potato supply system by Nyabyumba farmers to local NGOs[54]***




[54] *Ibid.*, p. 16. Reproduced with permission from the International Food Policy Research Institute <www.ifpri.org.>.

***Figure 2.3: Formal seed potato supply system by Nyabyumba Farmers' Associations[55]***




[55] Ibid. Reproduced with permission from the International Food Policy Research Institute <www.ifpri.org.>. The working paper from which figures 2.2 and 2.3. come can be found online at <http://www.ifpri.org/sites/default/files/publications/capriwp75.pdf>.

Public breeders from NARO obtain potato clones from the International Potato Centre (CIP).The clones are increased and evaluated at Kalengyere research station in Kabale district and in subsequent extensive on-farm trials in different agro-ecological zones. Final selection of a new clone is done in the 4th year of evaluation based on yielding ability, adaptability, resistance to late blight, bacterial blight and viruses, palatability and adaptation to the farming systems in the different agro-ecological zones. Varieties are then presented to the national variety release committee which releases the varieties. The released varieties are shown in the figure below.

***Figure 2.4: Potato varieties released in Uganda***

| Variety | Year of release |
|---|---|
| Rutuku (Uganda 11) | 1973 |
| Malirahinda | 1972 |
| Makerere | 1974 |
| Sangema | 1980 |
| Cruza | 1984 |
| Victoria | 1992 |
| Kisoro | 1992 |
| Kabale | 1992 |
| NAKPOT 1 | 1999 |
| NAKPOT 2 | 1999 |
| NAKPOT 3 | 1999 |
| NAKPOT 4 | 2003 |
| NAKPOT 5 | 2003 |
| KACHPOT 1 | 2006 |
| KACHPOT 2 | 2006 |

*Source: Regional Potato and Sweet Potato Improvement Network (PRAPACE)*

### 2.2.3. Seed Potato MultiplicationTechniques

There are both formal and informal multiplication techniques. Informal seed potato multiplication is done either through selecting tubers after harvesting or through negative positive selection in the field or separate 'seed plots'. In the latter system farmers set aside a separate plot that is exclusively used to plant seed. Negative mass selection means that the farmer rogues out plants that are not true to type or diseased, and harvests the bulk as seed. In positive mass selection, on the other hand, individual plants that are excellent are staked and harvested for seed whereas the main plot is harvested as food crop.

In formal multiplication the two mechanisms above can be used with a refinement that the selected plants may be planted during the subsequent season in lines to see whether any diseases were 'hidden' in the selection. Such 'clonal units' are then removed when any defect

is observed in one or more plants. The resulting breeders' seed[56] stock is planted in the following season. The resulting super-elite and elite (or foundation seed[57]) is then given to contracted seed potato growers who in turn produce seed potato for sale.

Obviously, these methods lead to a slow build-up of a good stock of seed potatoes. Therefore, rapid multiplication techniques have been developed which may be applied in formal seed potato production. These use stem, sprout or leaf bud cuttings. Propagation from stem cutting is also used to rapidly multiply improved pathogen-tested tubers or mini tubers. The seed tubers are replanted the following seasons to produce a stock for further multiplication. The production of guaranteed disease-free seed potatoes is thus a complex and expensive exercise which needs to be followed up by some more generations of closely reviewed multiplication to obtain the right quantities and qualities.

### 2.2.4. Demand Driven Access to Seed Potato - Informal System

The dominant source of seed potato in Uganda is farmers' own fields and neighbours. Farmers who reproduce their own seed potato take the right size tubers from the harvest bulk to save as seed potato for the next planting. More advanced farmers select in the field an area that is least affected by diseases and take tubers only from that area. Again, further advanced farmers plant a special plot to reproduce their own seed potato, which receives special care – particularly in terms of disease control. In Uganda, 11% of the farmers actually produce their seed potato in a separate plot. Some farmers (4%) purchase seed potato from seed potato growers. The rest of the farmers obtain seed potato from their own field, neighbours and the rural market. Regarding renewal of seed potato, only 26% of the farmers renew their seed potato and do so after an average of six seasons, implying that only 4% of the seed potato stock gets renewed each season.[58]

[56] Refers to seed potato supplied by breeder for multiplication after a variety is released. Multiplication may be done by seed potato companies in a way that maintains genetic purity of the variety and such seed is not available for sale to the public.

[57] This is seed potato handled as to most nearly maintain genetic identity and purity of the variety as at the time of release. It is produced under the responsibility of the breeder and a government agency or seed company can also produce this seed potato.

[58] See Gildemacher *et al.* 2009, p. 376.

***Figure 2.5: A comparison of the formal and informal seed potato systems***

| Characteristic | Formal | Informal |
|---|---|---|
| Seed source | NARO is the sole source of disease free starter seed | Farm-saved seed |
| Seed multiplication | Done by specialised seed growers | Farmers multiply own seed on-farm |
| Quality control | Done by seed inspectors to ensure quality control through seed certification that results in disease free planting material | No established regulations to control the exchange of seed tubers with seed borne pathogens |
| Amount of seed supplied | Small quantities of seed supplied | Large quantities of seed produced |
| Major actors | Specialized seed growers | Dual producers for both seed and ware potatoes and attracts very few specialized seed growers |
| Cost of seed vs. yield | Seed is sold at a high cost which is compensated for by the resulting high yields | Seed is relatively cheap but results into low yields |

*Source: Wagoire et al. 2005 and Gildemacher et al. 2009.*

The figure above reveals that formal seed systems have specialized seed growers who produce certified seed potatoes (under stringent quality requirements). However, this system is not developed in Uganda yet. On the other hand, the informal seed system produces both seed and ware potatoes in Uganda and in the absence of an operating certification system it is important to devise alternative means to reduce the disease pressures.

### 2.2.5. Intellectual Property

One of the major constraints to increased production of potato in Uganda's smallholder farming households is lack of access to quality seed potatoes.[59] Biological quality that includes the level of disease infection and physiological age of the seed potatoes is emphasized. Currently, IP does not play a role in the field of seed potato supply in Uganda. CIP does not claim ownership over technologies and varieties and attempts to develop organized seed systems that are able to operate without donor (NGO or government) support.

Since seed health issues are more important for potato growers than variety characteristics, the introduction of Plant Breeder's Rights is unlikely to have a major positive effect on private seed potato sector development. However, if new resistant varieties would enter the market that have a marked impact on disease incidence, then the variety and seed potato quality issue will be linked and more commercial channels might develop, at least until all farmers have the resistant varieties.

[59] See Gildemacher *et al.* 2009, p. 376.

If CIP decided to patent improved materials, this would greatly negatively impact access to improved varieties when Kalengyere research station would receive fewer genetic materials and this would limit research and innovation.

**Box II-3:** ***Highlights of CIP's IP policy (2006)***

*CIP holds as its basic Intellectual Property Policy the pursuit of publication and full disclosure into the public domain of these products and knowledge and actively encourages the sharing of materials, data, and information generated by CIP. CIP will, however, consider acquiring intellectual property rights (IPRs) on CIP-generated products for the purpose of keeping such products in the public domain, and promoting and protecting their access by the resource poor and developing countries.*
*CIP will not regard intellectual property protection as a mechanism for securing funding upon which it may depend. Intellectual property protection might be sought in situations such as the following: to support public and private partnerships which pursue mission-based research or which develop and apply research results, to assure ready access by others to research products developed or funded by CIP, to avoid possible restrictions arising from "blocking" patents and to ensure CIP's ability to do research without undue hindrance, to facilitate the transfer of technology, research products and other benefits to the resource poor, including through commercialization or utilization of research products, to facilitate the negotiation and conclusion of agreements for access to proprietary technologies of use to CIP research and in furtherance of the CIP mission.*

Uganda does not have a national IP policy (See chapter 4) and yet it is thought that Plant Variety Protection (PVP) might stimulate public and private breeding as is the case with maize. The partners in the Durable Resistance against Phytophthora project (See chapter 6) that introduce improved breeding materials in the region, Wageningen UR, Cornell University and CIP, have identified IP as an important issue. The technology and material is available for African countries under a humanitarian use license, and the partners have to decide whether IP could promote or obstruct seed potato provision and the management and sustainability of the resistance genes developed. How these regulatory changes will impact the seed potato systems remains to be seen but we can forecast that Uganda is primarily interested in benefiting from technologies and not necessarily the IPRs that might go with it.

### 2.2.6. Conclusion

Since seed potato provision is such a complex issue, it is important that IP does not add to the complexity unless it promotes the breeding and availability of locally adapted improved varieties. There is a clear need for improved seed potatoes which calls for training of more potato breeders and revising the dissemination strategy. Seed potato saving and local exchange by smallholders should not be curtailed as it is the major means of seed potato exchange. It may not be easy for the diversity of NGOs involved to manage the responsibilities associated with IP rights. Therefore, IPRs that allow seed saving and local exchange should apply in potato. However, PBRs that prohibit farmers from exchanging PBR-protected seed potatoes they have harvested, and patents that do not recognize incremental innovation may hinder almost all the farmers from accessing and maintaining improved varieties.

## 2.3 Cassava

### 2.3.1 Introduction

Cassava is the third most important source of calories in the tropics, after rice and corn.[60] It is regarded an important food security crop that provides food to millions of people, because it produces calories cheaply and also has the ability to survive for a long time in the soil. In Uganda, cassava was introduced in the 1860s and it currently provides around 13 % of the daily caloric intake. Cassava is used by households in many different ways. Its roots are used as food; its leaves are a vegetable, while its stems can be used for planting, or as fuel for cooking. In addition, cassava is gaining importance as a starch and biofuel cash crop.

Cassava is presently grown throughout Uganda. NARO estimated that a total of 3.5 million metric tonnes of the crop were produced from 450,000 hectares of land grown until the 1990s. Outbreaks of pests and diseases challenged the crop since then: notably cassava mealy bug, green spider mite, cassava mosaic virus, and cassava brown streak disease.[61] The vegetative multiplication increases the risk of spreading diseases through the planting materials. In addition, there are the increasing challenges from recurring droughts, persistent low-input cultivation, and market limitations in form of a low shelf life, poor quality standards and lack of an effective and national cassava industrialization strategy. The heterozygous[62] nature of the crop, low fruit set[63] and susceptibility to inbreeding depression[64] undermine breeding initiatives aimed at improving its genetic potential. In this section, 'seeds' stands for the cuttings that serve as planting material.

### 2.3.2 Supply Driven Access to Cassava Seed Materials - Formal System

In Uganda, Cassava is among the high priority crops on NARO's research agenda and yet one of the major challenges of the cassava program has been to get new cassava varieties into the hands of smallholder farmers across rural Uganda. In order for the breeders to reach farmers, the National Network of Cassava workers (NANEC[65]) was put in place in 1991 through which an integrated strategy for multiplication and distribution of virus-free stocks of improved varieties was developed. The NANEC conducts on-farm trials, multiplies and distributes planting material of varieties preferred by farmers planned under the supervision of scientists from the cassava program.[66] In Uganda, cassava varieties have been bred using conventional[67] methods,

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60 See <http://www.fao.org/ag/agp/agpc/gcds/> (accessed on 1 July 2011).

61 See <http://www.naro.go.ug/Institute/Namulonge/Cassava.html> (accessed on 1 July 2011).

62 Cassava is a cross-pollinated plant that generates large genetic variation with each cross hence complicating the breeding process as more time is required to segregate the progenies.

63 Affects breeding in a way that genetic gain is lower in plants with a lower fruit set.

64 Refers to the reduction in vigor and productivity as a result of self pollination that has produced plants that are more or less similar in their genetic make-up.

65 Comprises of district cassava subject matter specialists, extension workers, farmers, district agricultural officers and sub county cassava officers.

66 Body mandated to carry out research and development activities on cassava improvement in the country. It aims at supplying adequate food and raw materials, stimulating production for export and improving quality of rural life while conserving the natural resource base.

67 Based on selection of parent plants with desirable traits to produce an improved clone.

although conventional breeding efforts in cassava have registered limited success worldwide due to the crop's heterozygous nature which makes it difficult to breed efficiently. Therefore, the Global Partnership for Cassava's Genetic Improvement[68] for which Uganda is a member aims at developing and using advanced biotechnologies such as genomics[69] to improve the crop. Up till now, international and regional collaboration of Uganda's NARO with organizations like International Centre for Tropical Agriculture (CIAT) and East African Root Crops Research Network has yielded the formal release of 12 clonal varieties named Nase 1 to 12 as shown in the figure 2.6 below.

***Figure 2.6: Cassava varieties released in Uganda***

| Variety | Year of release |
|---|---|
| Nase 1-4 | 1994 |
| Nase 5-9 | 1999 |
| Nase 10-12 | 2000 |

Further clones that are being conventionally bred await release. Various mechanisms are developed to improve the sanitary quality of planting materials, such as selection of clean stock plants, planting in isolation, restricted movement of diseased materials, use of varietal mixtures and rapid multiplication techniques.[70] However, some farmers tend to maintain the local varieties because of their attractive eating qualities and this gives room for improvement of such varieties through breeding by adding demanded agronomic traits, in particular disease resistances.

### 2.3.3 Demand Driven Access Access to Cassava Seeds - Informal System

Farmers access cassava planting materials through informal ways such as their own farm-saved planting materials and farmer-to-farmer exchanges where one identifies a variety with desired characteristics in another's field and obtains it through an agreed means of exchange. This is also true in other African countries like Malawi where farmers rely heavily on recycled planting materials.[71] Other farmers in Uganda access improved planting material from the out growers scheme that is normally concentrated around research stations.
Multiplication sites are also set up by NARO in various regions and districts and these sites are often run by farmer groups, NGOs, community-based organisations with an aim of getting healthy planting material close to the farmers. The sites are strategically located to ease distribution of the planting material to farmers which is usually done twice a year.[72] A similar situation exists in Malawi where the government is embarking on a community seed program for cassava multiplication by contracting smallholder farmers to produce planting material

68 An initiative launched by FAO in 2002 that brings together 30 of the world's leading experts in cassava research to improve cassava through advanced biotechnologies.

69 Study of the entirety of an organism's hereditary information.

70 Techniques that increase the ratio of the planting material to what has been planted *e.g.* tissue culture as the low ratio is a problem in vegetatively propagated crops like cassava.

71 Gwarazimba & Vincent 2009, p. 6.

72 See <http://www.asareca.org> (accessed on 1 July 2011).

that it then buys and distributes to needy farmers.[73]

***Figure 2.7: A comparison of the formal and informal cassava seed systems***

| Characteristic | Formal | Informal |
|---|---|---|
| Seed source | National Network of Cassava workers (NANEC) especially when planting a variety for the first time, and out growers scheme during succeeding planting of a new variety | Neighbors |
| Seed multiplication | Seed multiplication by the NANEC is initiated during field days | Seed multiplied by the farmers |
| Amount of seed supplied | Smaller quantities supplied | Large quantities supplied |
| Dissemination of varieties | The NANEC is responsible for dissemination of new improved varieties through field trials in various areas over the country | Farmer-to-farmer sharing of planting materials for indigenous varieties and recycled new improved varieties |
| Seed quality | Uses rapid multiplication techniques, selection of clean seed and restricted movement of diseased materials to ensure seed quality | Seed quality is maintained using appropriate selection criteria and indigenous storage methods such as burying seed in the soil |
| Knowledge sharing | Annual workshops held at appropriate locations for district cassava coordinators to review progress, plan for next season and update knowledge on improved technologies. | Farmers social networks are sources of new knowledge |

*Source: Otim-NAPE et al. 2005.*

### 2.3.4 Intellectual Property

Conventional cassava breeding currently is not restricted by IPRs in Africa, and results from the Cassava Biotechnology Network[74], an initiative started in the late 1980s showing that scientists in cassava producing countries have easy access to state-of-the-art knowledge in cassava research. However, now that cassava is globally transformed from a food security crop for poor people to an industrial crop for starch production for food, fuel and industrial

[73] Gwarazimba & Vincent 2009, p. 24.

[74] Established to bring together researchers working on cassava from national and international research institutes from developed and developing countries. The network stimulates the exchange of information, research material, techniques and research results through annual scientific meetings in different cassava producing countries.

purposes, the crop provides prospects for poverty alleviation among the resource poor farmers who mainly grow the crop. The global transformation also means that where initially cassava was a crop dependent upon public research, it is now attracting commercial investments at national and global levels. At the global level, Nigeria, which is the world's leading cassava producer, has put in place incentives such as provision of land and infrastructure, tax holidays and assistance in obtaining financing to encourage local and foreign investors to establish cassava processing industries with an option of either engaging in production and processing or buying the crop from local farmers and concentrating on processing activities.[75] At the national level, Agro-Genetic Technologies Limited (AGT), the first and only private company in Uganda using tissue culture techniques for propagating different crops on a commercial basis, has recently taken on cassava. AGT has set up several sales points (nurseries) and demonstration gardens in local farming communities where farmers can access tissue cultured plantlets and also be trained in the technology. The increasing involvement of the private sector may in future dominate cassava production and this is likely to significantly alter public interest in protecting the outcomes of such research in terms of (bio-) technologies and varieties in the near future as access to cassava technologies and materials is likely becoming restricted in the near future. Already, Donald Danforth Plant Science Centre in the United States used genetic modification to introduce a gene to confer resistance to cassava mosaic disease. Uganda got involved in this program in 2008,[76]which includes the establishment of institutional mechanisms to manage genetically modified organisms (GMOs), possibly including IPRs.

### 2.3.5 Conclusion

Cassava is an important food security crop producing calories cheaply. It is vegetatively propagated and is difficult to breed because of low seed set.[77] New varieties have been released and the organisation of the NANEC greatly assisted the uptake of new varieties in the country through well-managed multiplication and farmer-to-farmer exchange. Breeding in the public sector is done in international and regional networks and increasingly uses modern technologies. At this moment, IPRs are not resting on the planting materials in Uganda. However, this might change since cassava is becoming an important industrial crop for starch and biofuels. It is therefore likely that increased private sector involvement in cassava as a market crop, a cash crop, will result in restrictions on access to cassava genetic materials and potentially reduced public research for smallholder farmers. The latter is likely to benefit smallholder farmers in a way that the companies will buy their surplus cassava, increasing their income levels.

75 See <http://www.tradeinvestnigeria.com/investment_opportunities/231637.htm> (accessed on 1 July 2011).

76 See <http://www.sciencedev.net/fe/Article.aspx?Aid=720> (accessed on 1 July 2011).

77 Number of seeds lower than average and this limits the number of crosses to be done in breeding.

## 2.4 Beans

### 2.4.1 Introduction

The common bean (*Phaseolus vulgaris L.)* is the second most important protein source and the third most important source of calories of all agricultural commodities produced in eastern and southern Africa. In Uganda it is the most important pulse[78] crop and an important food for people of all income categories. Beans are especially important for the poor as a source of dietary protein who cannot afford animal products. In addition, beans also are an important export crop. In the period 2000-2006, Uganda contributed to the 3.3% of the world's common bean exports in eastern and southern Africa.[79] They are largely grown by women in smallholder farming households as an important crop for food, cash, and agro-ecosystem improvement.[80] Beans are produced primarily for home consumption and any excess production would be sold at market, thus providing both food security and income generation.

There is a wide genetic diversity in the region. New varieties are needed for two reasons: pest and disease resistance and to changing farming systems[81], and specific requirements by the markets, notably in terms of seed color and size. Pests and diseases can be rampant: bean fly combined with root rot caused a drop in production of 80% in 1995. Access to bean seeds is mainly through the informal system although some elements of the formal or commercial system are beginning to manifest themselves. The advantages and disadvantages of the local (informal) and commercial (formal) bean systems have been summarized in figure 2.8 below.

Beans are self-fertilizing and seeds can thus be re-sown without significant genetic deterioration. Farmers therefore reuse seed widely. This deters commercial seed companies from investing in improved bean seeds except for popular varieties,[82] where they are somewhat certain of the demand, or in cases of relief operations. This situation has compelled National Agricultural Research Institutes and other interested producers to look for alternative ways to popularize new varieties.[83] Of course one option would be to develop locally adapted bean varieties with better pest and disease resistance.

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78 Crops harvested solely for the dry seed and are important due to their high protein and essential amino acid content.

79 Katungi *et al.* 2009, p. 27.

80 Beans are leguminous plants with nitrogen fixation properties. In traditional smallholder farming systems, beans are often intercropped with maize and bananas.

81 Methodologies used to generate, evaluate and disseminate agricultural technologies in association with farmer participation.

82 These have a high yield potential, mature within a short time and have a high market demand.

83 David *et al.* 1997, p. 8.

***Figure 2.8: Comparison of the formal and informal bean seed systems***

| Characteristic | Formal | Informal |
|---|---|---|
| Bean genetic diversity | Focuses on a few varieties | Supply of multiple varieties |
| Agro-ecological suitability | Seeks widely adapted varieties | Seeks varieties adapted to micro-ecology e.g. intercropping |
| Means of accessing seeds | Varieties move only via cash and often at higher prices (up to 3 times the price for food beans) | Varieties move through seed gifts, and seed exchanges |
| Access to information about new varieties and techniques | Company promotion | Farmers access information on new varieties and techniques at demonstrations, field days and in social networks |
| Types of clients | Commercial farmers, and especially relief agencies | Potentially all farmers based on their interests and needs |
| Seed quality assurance | Promoted through certification. Potentially important for disease free seed | Promoted through "social certification" (i.e. "if you cheat me, my neighbours and I will know") |
| Capacity building | Benefits only seed stockists and other formal suppliers | Strengthens farmers' skills by encouraging experimentation |
| Amount of seed supplied | Less than 5% (and often 1-2%) | Over 95% |

*Adapted from: Rubyogo, C.J., et al. 2007, p. 5.*

### 2.4.2 Supply Driven Access Access to Bean Seeds - Formal System

Figure 2.8 above shows that much of the bean seed (over 95%) is supplied through the local informal seed system where farmers identify and exchange seed of multiple varieties during farmer field days, demonstrations and also within their social networks and local communities, without using any reliable means to determine the seed quality. The commercial bean seed system on the other hand supplies commercial farmers (20%), NGOs and other relief agencies (80%) using cash as the medium of exchange. It focuses on a few varieties that are widely adapted and whose quality is guaranteed through certification. Therefore, the commercial seed system does not cater for majority of Uganda's farmers as its seed is expensive and cannot be afforded by these farmers.

The ease with which farmers can reproduce their bean seeds reduces opportunities for commercial seed companies to make a profit on commercially produced seed hence the focus on supplying relief agencies. Even then, demand for new variety seed may create a temporary demand for seed which ceases after the relief agencies have supplied sufficient amounts of

seed to farmers.[84] IPRs such as breeder's rights may support such supply, but will restrict the reuse and exchange of farm saved seed.

### 2.4.3 Supply Driven Access Access to Bean Seeds - Informal System

The informal system is the major source of bean seed. Farmers obtain bean seed from their own farm-saved seed, farmer-to-farmer seed exchanges, and local grain markets. Due to the minimal genetic deterioration, the reduction of seed transmission of diseases through the careful hand-picking of discolored seed and the extensive knowledge of (mainly women) bean farmers with regard to the traits of the different varieties and the mixtures that they grow, the informal system for bean seed is exceptionally important. In addition, farmers may get seed from NGOs, which may also be obtained from local – informal – sources. Seed relief operations target internally displaced people, disaster affected areas and refugee rehabilitation even in the surrounding countries such as Sudan and Democratic Republic of Congo.[85]Such support to the informal seed system encourages farmers to experiment and as such reinforces farmers' skills in bean production.

### 2.4.4 Intellectual Property

IPRs that have privileges for small scale farmers such as the PBRs that allow farmers to save and re-sow seed on their own holdings and local exchange and sales could be employed, provided that national seed laws implement a liberal farm saved seed provision. However, given that farmer-to-farmer exchange (not allowed under UPOV 1991 and patent laws) of new varieties is the main way of transfer of improved varieties of beans, any patent or breeder's rights system affecting this would restrict innovation and challenge seed security. However, IPRs could create an incentive for investments in breeding, which means that absence of any effective IPRs that create revenue from bean farmers would necessarily leave bean breeding to public investment.

### 2.4.5 Conclusion

Beans are a very important crop, produced mainly by smallholders for home consumption and providing the prime source of proteins for the poor. Formal seed systems provide a very small portion of the seed used, mainly because genetic deterioration does hardly occur. However, diseases can be seed borne and can have devastating effects if farm-saved seeds are used. Informal systems have proven to be effective in popularizing new varieties. Any IPRs that restrict farm saving and exchange of bean seed by smallholders will have devastating effects on seed security of the farmers as farmer to farmer exchange is the main means of seed transfer. On the other hand, any Plant Breeders' Rights (PBRs) that allow farmer-to-farmer seed exchange will be a major disincentive for breeding of improved varieties.

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84 Rubyogo *et al.* 2007, p. 2.

85 Thijssen *et al.* 2008, p. 114.

## 2.5 Maize

### 2.5.1 Introduction

Maize is the most important food crop in terms of calories. It is grown by both smallholders and large commercial farms throughout the country but more in the south and west than the northeast. Until the mid-90s, the 1972-released open pollinated Kawanda Composite A variety was popular. Seed was produced and marketed by the Uganda Seed Project, a public seed enterprise. In the 1990s, private firms such as FICA (Farm Inputs Care Centre), East Africa Seeds and Harvest Farm Seeds entered the maize seed market and outcompeted the – by then - privatized Uganda Seed Project. Some foreign private firms like Monsanto have also entered the market with their own hybrids, but NARO continues to be the main source of new varieties.

### 2.5.2 Supply Driven Access to Maize Seed - Formal System

Most of open pollinated variety [86] seeds used in maize breeding in Uganda involve the testing of materials from international programs – mainly resulting from International Maize and Wheat Improvement Centre (CIMMYT). Genetic modification (GM) technology is not yet used in the country, but some GM varieties are under test in the region. Material transfer agreements (See Chapter 4) are signed in which CIMMYT just needs to be recognized as the source of the germplasm and not as the co-owner of the new variety.

The germplasm[87] received from CIMMYT is screened by researchers at NARO; promising varieties are identified and released or crossed with the already existing local germplasm. Multi-locational trials are carried out in the different agro-ecological zones in the country for a period of 3 successive generations to determine which varieties are best suited for a specific region. The breeders then multiply breeder's seed which is mainly sold to seed companies such as Victoria Seeds Limited, Nalweyo Seed Company (NASECO) and some farmers groups like Bakusekamajja Women's Development farmers' association in Iganga district to multiply and promote the released varieties. These seed companies have an agreement with NARO to supply them with breeder's seed every year.

When a new variety is ready for release, NARO offers the variety to all firms who want to multiply it. Even though there is no Plant Breeder's Rights system in Uganda, NARO may enter into an exclusive agreement with a seed company to multiply and promote a particular hybrid variety. Open pollinated varieties are always given on a non-exclusive basis. The seed company does not pay royalties to NARO, but they have to buy breeder's seed from the breeder (=NARO) for every round of multiplication. The price that NARO charges for this seed includes a fee for the use of the variety. Breeder's seed of open pollinated varieties is sold at 10 US$/kg; parent seed for hybrids is sold at 300 US$/kg. Obviously inbred parent seed is more expensive to produce. Certified seed is sold to farmers at approx. 1 – 1.5 US$/kg. The business of these local firms depends on an efficient public breeding system and is vulnerable to any problems that NARO may face such as inadequate funding or loss of key research staff. However, international companies operating in Uganda bring in their own varieties from

[86] Plants that grow true to type meaning that they are capable of producing seed from this season's plants, which will produce seedlings that will look just like the parent plant.

[87] Genetic material.

abroad, which introduces a completely new dynamic.

Some of the seed companies such as Victoria Seeds Company Limited and NASECO have the capacity to produce their own breeder's seed with assistance from breeders in National Crop Resources Research Institute. NASECO for example recently released a hybrid variety "Salongo" with high protein content aiming at solving the malnutrition problem in Uganda. This variety was developed in cooperation with a CIMMYT and ASARECA program funded by the African Development Bank. The project reports reduction from kwashiorkor in children and improved breast feeding when mothers are fed on this maize.[88]

***Figure 2.9: Amount of seed processed and sold by seed companies during 2003-2006***

| Crop | 2003 | 2004 | 2005 | 2006 |
|---|---|---|---|---|
| Maize | 1,565 | 4,490 | 2,890 | 3500 |
| Rice | 56 | 300 | 600 | 530 |
| Sorghum | 66 | 350 | 540 | 217 |
| Finger millet | 26 | 150 | 150 | 54 |
| Bean | 466 | 1050 | 890 | 400 |
| Groundnut | 130 | 360 | 290 | - |
| Sunflower | 16 | 300 | 400 | - |
| Soya bean | - | - | 100 | - |
| **Total** | **2,325** | **7,000** | **5,860** | **4,701** |

*Source: Kabeere and Wulff 2008, p. 78.*

The maize seed sales in 2006/07 were 5700t with 3500t being open pollinated varieties and 2200t being hybrid varieties.[89] This shows a marked increment in the sales that could be attributed to the growing interest of seed companies dealing in the crop. It is government policy to strengthen the private sector as this together with public-private partnerships is a cross-cutting issue in many of Uganda's policies. It is therefore not likely that the government will continue to support informal seed exchange through public sector-led initiatives.

### 2.5.3 Demand Driven Access to Maize Seed – Informal System

Despite the presence of a number of seed companies thriving on their maize seed business, maize also has an informal seed sector where farmers save seed from previous seasons and exchange it to avoid buying seed each year. Some of these farmers are satisfied with the lower quality of seed they buy from their neighbours or in the ordinary commodity market – which is cheaper than commercial seed and available in time. This is obviously more common in open pollinated varieties since hybrid varieties lose a major part of their hybrid vigour and uniformity when reproduced. A comparison of improved maize seed sales by seed companies in Uganda with other crops reveals that maize plays an important role in Uganda's economy with maize seed sales exceeding those of other crops as shown in the figure below.

88 For more details on quality protein maize, see ASARECA 2009. Available at Available at <http://www.asareca.org/resources/reports/QPM.pdf> (accessed on 1 July 2011).

89 Langyintuo *et al.* 2010, p. 325.

***Figure 2.10: Comparison of the formal and informal maize seed systems***

| Characteristic | Formal | Informal |
|---|---|---|
| Source of seed | Public research institutes and the private seed companies | Farmers and neighbors |
| Type of seed supplied | Prime source of hybrid seed | Prime source of open pollinated varieties |
| Seed production | Breeder's seed produced from public research | On-farm seed selection |
| Varietal development techniques | Conventional and biotechnology techniques | On-farm variety selection |
| Seed multiplication | Carried out by the emerging private sector especially hybrid maize | Seed multiplication done by the farmers |
| Seed varieties | Depends on improved seed varieties, both open pollinated and hybrid seed | Both modern and indigenous varieties |

*Source: CTA 1999.*

### 2.5.4 Intellectual Property

Even though there are no breeder's rights in Uganda, NARO can still control and obtain income from the commercialization of its varieties. This is done through licensing of its varieties to seed companies which pay a high price for the breeder's seed or a royalty when they multiply basic seed on contract with NARO. Exclusive licensing is done for hybrid varieties while open pollinated varieties are non-exclusively licensed. This practice is defended because without some level of exclusivity, commercial seed producers may not invest in taking up a new hybrid variety into their product mix especially as a new variety needs promotion, involves risks in terms of production, planning, and costs in terms of promotion.

Hybrid varieties provide a biological protection against re-use of farm-saved seed, similar to strong IPRs in as far as IPRs prohibit the seed producer from farm-saving of seed. IPRs may additionally protect a seed producer from other companies, its competitors. This could be an incentive for the private companies to do their own breeding. The improved hybrid or open pollinated varieties also create a benefit for the farmers through higher yields which will likely more than compensate the higher seed price. IPRs could also be an incentive for large foreign companies to bring parent materials of their own commercial hybrids.[90] In Malawi for example, Monsanto is unwilling to bring in superior technology of maize because the country does not have an effective IPR system to protect patented germplasm.[91] However, if strong IPRs that disallow farm-saving of seed would also apply to open pollinated varieties, then the informal production and/or exchange might be challenged.

Since quite a lot of patents are resting on commercial international maize materials, patent policies may also affect the maize seed sector significantly, which is an important policy issue for the country. Already, NARO has signed an agreement with Monsanto and

[90] Larson & Mbowa 2004, p.89.

[91] See Gwarazimba & Vincent 2009, p.17.

African Agricultural Technology Foundation (AATF) on the Water Efficient Maize for Africa (WEMA) project that focuses on drought tolerant maize whose genetic materials are patented elsewhere and this project has a number of restrictions on the further use of the products resulting from the project by NARO as expounded in Chapter 4.

### 2.5.5 Conclusion

Maize is a food crop grown by both small scale and large scale farmers in Uganda. A number of seed companies, both private and international, deal in the crop. Some international seed companies like Monsanto are reluctant to take their superior materials to countries that do not have effective IPR systems. The informal seed system is still the frequently used source of seed, which represents a potential for increasing commercial markets. Plant variety protection could support such developments in Uganda for open pollinated varieties as protection against farm-saving or exchange, but particularly for hybrids – as protection against competing companies. On the other hand, it is likely that with the patenting of maize genetic materials in Uganda, there will be mainly international seed companies, and since such patented traits are likely to be used only in hybrids, these are unlikely to reach remote and resource poor farmers. This could imply that such smallholder farmers would not easily access improved seed and this poses a risk to their food security.

## 2.6 Conclusions

### 2.6.1 Relationship Between Crop Characteristics and the Pull/Push Factors

From this Chapter, it is clear that the characteristics of different crops affect the development and strength of the push and pull factors. For vegetatively propagated crops like cassava and potato, farmers mainly obtain planting materials of improved varieties from farmer-to-farmer exchanges. A key element is obtaining disease-free planting material rather than a new variety. The breeders of such crops reach farmers with new varieties through farmer associations that produce seed in a semi-formal manner, or through field trials/ demonstrations, after which they share good materials with neighbours and kin. For self-fertilizing crops like beans where genetic deterioration is rare, the push factors are also weak as farmers re-sow their seed recurrently. Contrary to this, the cross-pollinated crops such as maize have strong push factors with many private and emerging international seed companies dealing in the crop, as they focus on hybrid varieties. This means that strategies that may work for maize may not be easily applicable to the other crops. Government seed policy is however based on an expectation that the private sector can handle all seeds.

### 2.6.2 Formal and Informal Seed Systems

The informal seed system is dominant in Uganda with farmer to farmer seed exchange as the major means of seed transfer unlike the formal seed system that uses cash. The formal seed system produces high quality seed that has undergone checks in the certification process resulting into higher prices. Generally, the informal seed systems have the advantage of very low seed costs; however, if the seed is of poor genetic quality, poor germination and poor health condition, the yield and quality of the resulting crop will also be poor. High quality seed

that is a characteristic of formal seed systems generates a better physical and financial yield, which more than compensates its higher price.

### 2.6.3 Current Role of IPRs on Access to Improved Seed

Generally, IPRs currently do not play a major role in the access of smallholder farmers to improved seed. The Seeds and Plant Act 2006, states that the Seed Board may grant breeders' rights of seeds on recommendation of the Variety Release Committee. This is however not implemented. That means that the Seeds and Plant Act, 2006, does not make reference to farmers saving their seed and re-using the seed, even if purchased from a plant breeder who has breeders' rights.[92] However, the rule that only certified seed is to be marketed creates a quasi-IPR. The person or institution holding the breeder's seed can control the subsequent seed production by handing this initial seed source to particular producers on an exclusive basis. NARO has thus been able to 'give' maize varieties and hybrids to particular producers which in turn create a market for themselves.

### 2.6.4 Future Outlook of IPRs in Uganda's Seed Systems

Assuming that the situation remains constant and Uganda's seed system remains under the dominance of the informal seed system, efforts need to be geared towards ensuring good quality seed, if MDG 1c is to be met. This will be achieved either through the government providing sufficient funds for public breeding or installation of systems such as IPRs that have the ability to create incentives for seed improvement through the private sector.

However, with the recent introduction of biotechnology in the breeding of crops such as potato and maize including the on-going trials for genetically modified maize in the region, we can predict that there will be a shift in the breeding technologies from conventional methods to including biotechnology techniques and this shift will lead to the availability of more improved seed. There will also be increased interest by the private sector in seed production and marketing, but private companies will thrive more with some level of exclusivity provided by a functional IPRs system such as PBRs.

[92] Kabeere & Wulff 2008, p. 43.

# CHAPTER 3 INTELLECTUAL PROPERTY REGIMES OF AFRICAN COUNTRIES AND IMPLICATIONS FOR ACCESS TO SEEDS BY RESOURCE-POOR FARMERS

*Godber Tumushabe & Julian Barungi*

**Abstract**

The achievement of MDG 1c through agricultural growth and productivity of smallholder agriculture requires agricultural technologies such as better varieties to be developed and that they reach farmers. Technology transfer is increasingly dependent on Intellectual Property Rights. While the on-going IPR policy reforms at the various levels present an opportunity for aligning national IPR policies towards achieving MDG 1c targets, there is an apparent knowledge gap on the potential impacts of IPR on access to agricultural technologies by resource-poor farmers. This Chapter analyzes the key factors that are shaping the development of IPR regimes in Africa and the potential implications of the emerging regimes on access to agricultural technologies. The Chapter seeks to answer the following key questions: What is the nature and character of the current national laws and policies on IPR and to what extent are these configured to facilitate access to agricultural technologies and the attainment of MGD 1c targets? What are the push and pull factors shaping the development of IP policies and laws on the African continent? To what extent are institutions managing the reform processes capable of ensuring that IPR regimes take into account the need to ensure that national IPR regimes contribute to the attainment of MDG 1c? Analysis of the current legal framework for IPRs in Uganda and their key institutions shows that IPR reforms are currently managed by institutions that are not directly mandated to support resource-poor farmers. In the absence of effective institutional coordination, issues of access to agricultural technology by resource-poor farmers may be marginalized in the on-going policy reform processes. A discussion on the push and pull factors shaping IP reforms in Africa concludes that most of the reforms are driven by interests and mandates of major external actors such as WTO, WIPO, UPOV and other multilateral and bilateral agencies. We then point at potential future directions of a more balanced IP policy regime in Uganda and its impact on access to agricultural technologies by resource-poor farmers.

## 3.1 Introduction

This Chapter examines the current trends in the development of Intellectual Property Rights regimes in Africa, the key influencing factors and how these regimes impact on agricultural R&D and access to new seed varieties by resource-poor farmers. By looking at the case of Uganda, we analyze the formal policies at national and institutional levels and what the drivers are/have been to arrive at these, and also investigate the perceptions and actual practices of IP management. These investigations form the basis of an analysis of the coherence of IPR policies at different levels and of the consequences of IPRs with respect to the use of technology in research and the direction of research programs in favor of, or away from, the interests of resource-poor farmers.

The discussion in this Chapter is presented in five sections. The section after this introduction is an analysis of the current legal framework for IP in Uganda and its implications for access to agricultural technology. We then provide a brief analysis of the key institutions that are mandated to manage IPR policy and legal reforms. The fourth section is a broader

discussion on the push and pull factors shaping IP reforms in Africa, which finally leads to a focus on the potential future directions if IP policy regime in Uganda and how this regime will impact on access to agricultural by resource-poor farmers and the attainment of MDG 1c.

## 3.2 Legal Framework for Intellectual Property in Uganda and Implications for Access to Agricultural Technologies

### 3.2.1 Post-colonial IP Legislation

Like many other African countries, the legal regime for the protection of intellectual property has evolved over the last half century with its antecedents in the colonial legal system. A number of studies have shown that since independence in 1962, Uganda's post-colonial governments enacted IP legislation to spur industrial development and technology transfer, mainly in the form of attracting foreign direct investment (FDI). For example, the immediate post-independence legislation, such as the Uganda Industrial Act 1963 and the Foreign Investment (Protection) Act 1964, sought to create a favorable legal environment to stimulate the transfer of technology by promoting foreign and domestic investment.[93] For example, the Foreign Investment (Protection) Act specifically prohibited the compulsory acquisition of property belonging to foreigners. The Act also made special provisions for the repatriation of profits by foreign investors.[94] According to these studies, the first decade of independence saw a dramatic increase in FDI. However, this trend reversed as Uganda adopted a more state-driven economy, and from the early 1970s, expropriated properties of foreign nationals.

During the 1970s, the only visible initiative to attract FDI was the promulgation of the Foreign Investment Decree of 1977.[95] The Decree exempted foreign investors from import duty and sales taxes on plant and machinery for investment in approved enterprises.[96] A number of agriculture-related enterprises, including fish processing, the sugar industry, the textile industry and the leather industry were scheduled areas of investment. It is important to note that these exemptions were not retrospective and only applicable if the investment exceeded US$571,000.[97]

Besides investment-related legislation, Uganda also inherited the colonial system of IP at independence. A set of colonial legislation covered key areas such as patents, industrial designs, and copyrights. In the case of patents, two pieces of legislation are particularly relevant to show the importance of colonial law today: The Patents Act 1964[98] and The United Kingdom Designs (Protection) Act.[99]

The Patents Act 1964[100] was designed along similar lines as the United Kingdom Designs (Protection) Act. The 1964 Patents Act provided that any grantee of a patent in the United

93 Obwona 2004 and Ikiara 2003.

94 *Ibid.,* Section 3.

95 Foreign Investment Decree, No. 18 of 1977.

96 *Ibid.*, Section 1.

97 The exchange rate in 1977 was US$1=8 Uganda Shillings.

98 Patents Act, 1964.

99 Cap 84, Laws of Uganda, Revised Edition, 1964. (Ord. 6, June 1937, L.N.261 of 1962). Also see Patents and Designs Act of the United Kingdom, 1907-1932.

100 The Patents Act, Cap 82. Laws of Uganda, 1964 Edition.

Kingdom, or any person deriving his right from such grantee by assignment, transmission or other operation of law, could apply to have such a patent registered in Uganda. The application was to be made within three years from the date of the grant of the United Kingdom Patent.[101] Such registration conferred the same rights as conferred by the United Kingdom registration subject to conditions established by Ugandan law.

These laws were essentially designed to protect proprietary technologies that were granted protection in the United Kingdom and largely dealt with the administration of such IP in Uganda. They did not articulate any policy directions on intellectual property, nor did they seek to create any incentives tailored to Uganda's peculiar economic environment as an agriculture-based economy.

IP legislation inherited from the colonial legal regime thus did not have any specific relevance to agriculture or the technology needs of resource-poor farmers. This is mainly because the legislation was mainly designed to protect the interests of British innovators in Uganda.

### 3.2.2 Contemporary IP Legislation for Uganda

Consequently, Uganda's current legislation on intellectual property has mainly developed over the three decades beginning in 1978. In that year, Uganda joined the African Regional Industrial Property Office (ARIPO).[102] The broad objective of ARIPO is to promote the harmonization and development of the African industrial property laws, establishment of common services and to assist members in the acquisition and development of technology relating to industrial property matters. In 1984, Uganda signed and ratified ARIPO's Harare Protocol on Patents and Industrial Designs.[103]

It has been argued[104] that the ARIPO treaty regime has had two profound impacts on Uganda's IP rights law. First, the ratification of the Harare Protocol signalled the beginning of an era whereby proprietary technology could be patented in Uganda through the ARIPO Office. This means that any empirical study seeking to understand the patenting trends in the country ought to start with the ratification of the Protocol. Secondly, the work of ARIPO regarding harmonization, training and provision of common examination services has had an enduring influence on the trajectory of IP law reforms in Uganda. However, it is also important to recognize that the ARIPO regime is modelled along the same orthodoxy as the international IP architecture - the presupposition that effective protection and administration of IP is what is needed for countries to attract technology transfer and foreign direct investment. It is this same orthodoxy that underpins the IP legal reforms undertaken by Uganda from the early 1990s to the present.

Notably however, Uganda is not a member of the convention for International Union for the Protection of New Varieties of Plants (UPOV[105]) that aims at promoting an effective system of plant variety protection, with the aim of encouraging the development of new

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101 *Ibid.,* Section 4.

102 ARIPO is established by the Agreement on the Creation of the African Regional Industrial Property Office (ARIPO) adopted at Lusaka, Zambia on December 9, 1976.

103 See Harare Protocol on Patents and Industrial Designs Within the Framework of the African Regional Industrial Property Organization (ARIPO) 1982, Harare.

104 Tumushabe 2007.

105 See Chapter 1.

varieties of plants, for the benefit of society. Uganda is an observer in the UPOV Council and it has been in contact with UPOV's office for assistance in the development of laws based on the UPOV Convention[106]. It is also important to note that later revisions like UPOV 1991 increase protection of plant breeders' rights as they make farmers' privilege optional[107] and yet farmers comprise the majority of Ugandans.[108] The UPOV Secretariat appears not very sensitive to the reality of developing countries where local exchange is both a necessity from the point of seed security, and a useful mechanism for dissemination of new technologies among farmers who are not connected to input markets.

Uganda's contemporary IP legislation, therefore, includes the traditional industrial property protection legislation as well as legislation governing investment, science and technology and, agriculture research and development. The next sub-subsection briefly analyzes the IP content of key pieces of legislation enacted over the last two decades.

### 3.2.3 The Investment Code Act

The Investment Code Act was first enacted in 1991.[109] In 2000, it was codified in the 2000 Edition of the Revised Volume of the Laws of Uganda.[110] The Act contains a number of provisions on technology transfer. Part VI of the Act entitled, "Agreements for the Transfer of Foreign Technology and Externalization of Funds," requires the Uganda Investment Authority (UIA) to register every agreement for the transfer of foreign technology or expertise.[111] The Act enjoins the executive director of the Authority to maintain "a register in which shall be recorded all agreements for the transfer of foreign technology or expertise." The Act imposes a number of conditions that must be contained in a technology transfer agreement. Among other things, the conditions cover royalty payments and fees, provision of technical assistance, timeframe by when payment of royalties or fees may cease, or the continued supply of spare parts and raw materials with respect to the respective technology.[112] But Section 30(2) prohibits the inclusion of certain conditions from an agreement for technology transfer. These include prohibitions on the following restrictions: use of other competitive techniques; manner of sale of products or exports to any country; source of supply of inputs; and limits on the ways in which any patent or other know-how may be used.[113]

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106 UPOV Press release No. 82, 2010. Also available at http://www.upov.int/export/sites/upov/en/news/pressroom/pdf/pr82.pdf.

107 Naluwairo 2006.

108 According to the Uganda Bureau of Statistics, 78.9% of Uganda's 13 million households are either directly or indirectly dependent on agriculture. See UBOS (2007). Uganda Demographic and Household Surveys (UDHS) 2006/07, Kampala.

109 Investment Code, Statute No.1 of 1991. (For purposes of this study, both the Investment Code of 1992 and the Invest Code Act 2000 are referred to as the Investment Code or the Code).

110 The Investment Code Act, Cap. 92.

111 *Ibid.,* note 63, section 29(1).

112 *Ibid.,* section 30(1).

113 Section 30(3) provides that the Uganda Investment Authority may exempt an investor from any of the provisions of sub-section (1) or (2).

### 3.2.4 The Patents Act

The Patents Act[114] which was enacted around the same time as the Investment Code Act sought to modernize Uganda's legislation on patents. In his presentation of the Patents Bill that formed the basis for the Act, then Minister of Justice George Kanyeihamba pointed out that the main purpose of the proposed legislation was "to provide a modern law on patents which will make independent, substantive and comprehensive provisions for the manner in which patents may be granted, registered and protected in Uganda in the context of our treaty obligations under ARIPO…" The bill also made reference to Uganda's obligations to implement the provisions of the Paris Convention for the Protection of Industrial Property, 1883.[115]

The Patents Act and its subsequent amendment in 2000[116] clearly show that its overriding motivation was to ensure compliance with Uganda's obligations as incurred under a series of international instruments on intellectual property (see Figure 3.1). The Act incorporates the right of priority as set out in the Paris Convention.[117] It gives patents that have been granted by ARIPO (ARIPO patents) legal effect in Uganda if the application designates Uganda as a country of protection. The Act empowers the Registrar of Patents to make any necessary modifications to the grant and to communicate in writing that a particular patent shall not be given effect in Uganda.[118]

***Figure 3.1: Selected Intellectual Property Rights Agreements and International Organizations to which Uganda is a Party***

| Membership of WIPO Treaties | Membership of other relevant Treaties | Membership of Regional Bodies and Instruments |
|---|---|---|
| Paris Convention for the Protection of Industrial Property 1983 (Since June 1965) | Agreement Establishing the World Trade Organization (WTO) 1994 effective since January 1995) | African Regional Intellectual Property Rights Organization (ARIPO) 1976 (Since August 1978) |
| Convention Establishing the World Intellectual Property Organization (WIPO) 1967 (Since October 1973) | Agreement on Trade Related Aspects of Intellectual Property (TRIPs) 1994 (Since January 1995) | Harare Protocol Patents and Industrial Designs Within the Framework of the African Regional Industrial Property Organization (ARIPO) 1982 (Since April, 1984) |

114 The Patents Act, Cap 216, Laws of Uganda, Revised Edition, 2000

115 Dr. George Kanyeihamba, Minister of Justice/Attorney General, 1991 while presenting The Patents Bill for the Second Recording. See the Hansards, Wednesday 29th May, 1991.

116 The Act was amended in 2000 to make provisions for the implementation of the Patent Cooperation Treaty (PCT).

117 Patents Act, section 16.

118 *Ibid,* section 23. As shown in Chapter 4, there is no record that the Registrar has ever modified any patent grant to address the technology transfer interests of Uganda. The malfunctioning of the Registry means that there is no systematic recording or review of the patents applications coming through ARIPO.

| | | |
|---|---|---|
| Patent Cooperation Treaty 1970 (Since February 1995) | Convention on Biological Diversity 1992 (since 1993) | Treaty Establishing the East African Community |
| Patent Law Treaty 2000 (Since June 2000) | | |

The Patents Act also incorporates the universally applicable features of the patent system with limited exceptions. Section 7 of the Act provides that for the purposes of the Act, "invention" means a solution to a specific technological problem and may be, or may relate to, a product or process.[119] With respect to agricultural related technologies, the Act excludes the following from patentability: (i) discoveries and scientific and mathematical theories; (ii) plant or animal varieties or essentially biological processes for the production of plants or animals, other than biological processes and the products of those processes.[120]

The incorporation of the Patent Cooperation Treaty into the Patents Act also demonstrates that conformity to international standards is the fundamental motivation behind Uganda's patent legislation.[121] The Patent Cooperation Treaty[122] extends the minimum standards of IP protection by providing what in the treaty is referred to as the "International Application."[123] In this regard, the Patents (Amendment) Act creates a mechanism to affect the administrative procedures contained in the treaty. Not surprisingly, the Records of Parliament (Hansards) show that the legislative motivation for the approval of the bill for this legislation[124] was Uganda's ratification of the treaty. In its report to Parliament on the proposed bill, the Committee on Legal and Parliamentary Affairs stated its recommendation in the following terms: "Since the Bill lifts provisions from the Treaty (PCT), which Uganda committed it to; the Committee recommends that it should be passed into law." Neither the bill nor the parliamentary committee makes any reference to the need to promote agricultural R&D and facilitate the transfer of foreign agricultural technologies.

### 3.2.5 The Patents Act and Resource-poor Farmers

The Patents Act (as amended) provides three situations in which Uganda can exercise discretion to address the special needs of the country such as those regarding access to new agricultural technologies by resource-poor farmers.[125]

First, section 12 of the Act provides that: "The Minister may, in the public interest, by statutory instrument, exclude from patentability, inventions concerning certain kinds of products or processes for the manufacture of those products, for a period not exceeding two years." However, there is no precedent to suggest that agricultural technology patents would be construed to fall within this "public interest" exemption.

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119 This scope of patentable subject matter is generally consistent with Article 27(1) of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs Agreement), 1994. See WTO 1995.

120 This exception is consistent with Article 27(2)(b) of the TRIPs Agreement.

121 See The Patents (Amendment) Act, No. 7 of 2002.

122 Patent Cooperation Treaty 1970, Washington D.C (as in force from April 2002).

123 For details on the "International Application", legal effect and filing date, see *Ibid.*, Article 1, 8 and 11.

124 See the Patents (Amendment) Bill 1991. Also see Parliament of Uganda 2002.

125 Tumushabe 2007.

Secondly, the Act imposes a set of four exceptions to the rights of the patent owner. These are: (i) acts done in pursuance of scientific research; (ii) acts done in respect of articles which have been put on the market in Uganda by the owner of the patent or with his or her express consent; (iii) the use of the patented article in foreign aircrafts, land vehicles or vessels of other countries which temporarily or accidentally enter the airspace, territory or waters of Uganda; (iv) certain good faith acts performed before the filing or the priority date of the application. The research exemption may be particularly relevant to the transfer of agricultural technologies and provides Uganda with an opportunity to build its own domestic innovation and technological capacity, depending on its interpretation with regard to the width of the exemption.

The third situation presented by the Patents Act that can be exploited to promote the transfer of technology in general and agriculturally relevant technologies in particular is the compulsory licensing provisions contained in Section 30 of the Act. A judicial application for a compulsory license may be brought to court "any time after four years from the filing date of an application or three years from the grant of a patent…"[126] Such an application has to be based on any of the following grounds:

i. That the patented invention, being capable of being worked in Uganda, has not been so worked;
ii. That the existing degree of working of the patented invention in Uganda does not meet on reasonable terms the demand for the patented product on the domestic market or for the purposes of exploitation;
iii. That the working of the patented invention in Uganda is being hindered or prevented by the importation of the patented product;
iv. That, by reason of the refusal of the owner of the patent to grant licenses on reasonable terms, the establishment or development if industrial or commercial activities in Uganda, or possibilities of exportation from Uganda, are fairly and substantially prejudiced.

Proponents of strong IPR protection may view these provisions as detrimental to the proprietary interests of the patent holder and may point to these provisions as an explanation of why the Act has not triggered substantial patenting activity. However, such concerns are unfounded because the Act requires due process of the law for such a compulsory license to be issued.

### 3.2.6 The National Council for Science and Technology Act

Lastly, another important piece of IP related legislation is the Science and Technology Act (1990)[127] which establishes the Uganda National Council for Science and Technology (UNCST). The UNCST is vested with the mandate to advise on and coordinate the formulation of an explicit national policy on all fields of science and technology, and to assist in the promotion and development of indigenous science and technology. With particular reference to access to agricultural technologies, it is important to recognize that UNCST is the focal

[126] Patents Act, section 30(1).

[127] Chapter 209 of the Laws of Uganda 2000.

organization responsible for biotechnology activities in the country including the formulation of appropriate policy and legislation governing the application of agricultural biotechnology in general and genetically modified organisms (GMOs) in particular.

In conclusion, it is important to recognize that the above laws so far represent the state of the existing legal regime governing intellectual property in the different fields of scientific and technological endeavours in Uganda. These laws do not contain specific provisions to direct the course of agricultural R&D towards the technological needs of smallholder farmers or the attainment of MDG 1c. In addition, besides the UNCST which handles biotechnology issues, the rest of these laws fall under the mandate of agencies such as the Uganda Registration Services Bureau or Uganda Law Reform Commission that do not directly handle agricultural related issues such as access to agricultural technology.

However, it is important to recognize that a number of reforms are currently on-going and point to the fact that the IP policy, legal and institutional landscape may change dramatically over the next year.

## 3.3 Institutional Framework for IP Policy Formulation and Implementation in Uganda

This section analyzes Uganda's emerging institutional landscape in terms of its roles in the facilitation or undermining of the use of IP to increase access to agricultural technologies and the attainment of the relevant MDG 1c targets.

A country's ability to harness IP to improve access to technology by resource-poor farmers and the attainment of MDG1 targets is also contingent upon the way national institutions responsible for IP interact with the rest of agencies responsible for development policy. For example, the country's IP institutional architecture must be configured in such a manner as to enable scientists, innovators and enterprises to access the pool of scientific knowledge disclosed through IP filings and grants.

There are at least four major institutions that are at the centre of developing IP policy and legislation in Uganda:

### 3.3.1 Uganda Law Reform Commission

The Uganda Law Reform Commission (ULRC)[128] is a body established under the Constitution of Uganda, 1995.[129] Its main mandate is to study and keep under constant review the laws of Uganda with the view of making recommendations for their systematic improvement, development, modernization and reform. The Commission has been engaged in the reform of IP laws within the context of the Commercial Justice Reform Programme. This program was designed as part of the reforms under the Medium Term Competitive Strategy (MTCS) aimed at improving the business environment for the private sector.[130] The Commission has therefore been taking leadership in the reform of key IP legislation by undertaking a series of

[128] The ULRC was established in 1990 by the Uganda Law Reform Commission Act, Cap. 25, Revised Edition of the Laws of Uganda, 2000 and subsequently established as a constitutional body under Article 284 of the 1995 Constitution of Uganda.

[129] See <http://www.ulrc.go.ug/about_ULRC/ulrc_brief.php> (accessed on 1 July 2011).

[130] See <http://www.finance.go.ug/project_ongoing.php#fifteen> (accessed on 1 July 2011).

studies and proposing appropriate legal reforms. In 2004, a series of study reports and bills covering copyright and neighboring rights, industrial property, traditional medicine practice, trademarks and service marks, trade secrets, plant variety protection and competition law were published by the Commission.

### 3.3.2 The National Council for Science and Technology

The Uganda National Council for Science and Technology (UNCST)[131] is a statutory body established under the Uganda National Science and Technology Act.[132] The broad mandate of the Council is to develop and implement policies and strategies for integrating science and technology into national development policies, to advise government on policy matters regarding the promotion of science and technology and, coordinating and guiding national research and development.[133]

The UNCST provides leadership in the development of national policy and legislation and has been at the forefront of promoting the development of IP policies at agricultural and other research institutions in Uganda. In 2010, the government adopted a new National Science, Technology and Innovation Policy developed under the leadership of the Council. Among other things, the government of Uganda commits itself to facilitate and encourage science and technology innovation through protection and use of Intellectual Property Rights.[134] In relevant parts, the government commits itself to establish a full-fledged national IPR office to undertake searches, formal and substantive examinations, grant and register patents, trademarks, copyrights and other IPRs. Equally important, there is an explicit policy commitment to facilitate the setting up of institutional support systems for production, protection and commercialization of innovations and artistic works as well as incorporation of aspects of IPR into the school curricula at the various levels of education in order to improve awareness.

With particular reference to agriculture, it is important to recognize under the National Science, Technology and Innovation Policy, that the government commits itself to "facilitate protection and beneficial exploitation of indigenous technologies." This commitment may be interpreted to imply the government commitment to protect informal seed systems so that they work side by side and complement formal seed systems. In addition, through its National Biosafety Committee, the UNCST has the mandate of approving the introduction ofGMOs including genetically modified seeds in the country.

### 3.3.3 The Uganda Registration Services Bureau

The Uganda Registration Services Bureau (URSB) is a statutory agency[135] to (i) administer and give effect to the relevant laws (ii) provide registration services, (iii) collect and account for revenue, (iv) advise the government on matters relating to registration services under the relevant laws, and (v) assist the government in the formulation of policy relating to the collection of revenue.

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132 Chapter 209, Revised Edition of the Laws of Uganda, 2000.

133 See <http://www.uncst.go.ug/site/index.php> (accessed on 1 July 2011).

134 Republic of Uganda 2010. Ministry of Finance, Planning and Economic Development, p. 3.

135 Chapter 210, Revised Edition of the Laws of Uganda, 2000.

The Bureau's work on IP is mainly related to registration and compliance. The Bureau is also the main channel of technical assistance programs delivered by the World Intellectual Property Organisation (WIPO).

### 3.3.4 Ministry of Trade, Tourism and Industry

The fourth major institutional player as far as national policy on IP is concerned is the Ministry of Trade, Tourism and Industry (MTTI). The MTTI is the government of Uganda agency responsible for coordinating all matters relating to international trade negotiations and the implementation of the relevant international trade agreements. The ministry is also responsible for the formulation and implementation of national trade policies.

Under the National Trade Policy adopted in 2007, IP is considered a cross-cutting issue that cuts across a wide range of disciplines. Under the policy, government commits itself to "develop and formulate laws and policies to protect Intellectual Property Rights, with a view to, inter alia, protect Uganda's genetic resources, and encourage innovativeness."[136]

The MTTI is also the host of the Inter-Institutional Trade Committee (IITC), a multi-stakeholder platform that brings together stakeholders engaged in trade and other related sectors. Membership of the IITC draws from all the key government agencies that cover various trade areas including agriculture. The National Trade Policy recognizes and formally establishes the IITC as the consultative mechanism between public and private sectors for trade policy formulation and policy implementation.[137] The committee includes membership from key sectors such as agriculture, environment, science and technology and other key players such as the Uganda Law Reform Commission.

Throughout the Doha Round of Trade Negotiations, the IITC had a very active sub-committee on IP focusing on elaborating Uganda's negotiating positions on the Trade-Related Aspects of Intellectual Property Rights (TRIPs) Agreement. According to some ministry officials, the work of the sub-committee wound up some years back and IP issues are supposed to be handled by the plenary of the IITC. However, in principle, the IITC provides the only visible multi-stakeholder platform for ensuring convergence in IP policy formulation, policy implementation and generally the mutual interface between IP as a trade policy instrument on the one hand and as a development policy instrument on the other.

The major challenge for Uganda is that most of the work including the policy reforms and capacity building activities being undertaken by these agencies is heavily financed by donors and delivered through technical assistance programs. Some of the visible players include United States Agency for International Development (USAID) for biotechnology, WIPO for IP registration services and compliance with WIPO agreements, and the World Trade Organization for trade-related aspects of IP. In the case of the later, the Joint Integrated Technical Assistance Programme (JITAP) and the Integrated Framework (IF) are the main channels through which technical assistance including support to the IITC is channelled. As discussed in the next section, such technical assistance is heavily biased towards the implementation of the respective agreements (usually protecting the interests of donor countries) and less focused on the need to address the priority needs of the country,

136 Republic of Uganda 2007.

137 *Ibid.*, p. 19.

amongst which are the technology needs of resource-poor farmers and the national efforts to achieve MDG 1c.

### 3.4 Factors Influencing IP Policies in Africa

The current push for IP policies especially in the agricultural sector are a recent phenomenon dating back to the late 1980s and the beginning of the 1990s, probably related to the onset of agricultural biotechnology. However, in the period after the completion of the Uruguay Round of Trade Negotiations and adoption of the TRIPS Agreement,[138] the push for harmonizing or development of IP policies assumed unprecedented urgency. Besides the raging debate on IP and access to medicine, nowhere has the discourse in intellectual property courted more controversy and dominated public policy than in agriculture and with particular reference to access to new agricultural technologies by resource-poor farmers in Africa. Indeed, over the last decade, African countries and institutions have engaged in processes to enact or revise their policies and laws on IP while also developing initiatives aimed at strengthening IP regimes.

To understand the factors influencing the development of IP regimes and their implications for access to seeds by resource-poor farmers, it is important to approach the subject from at least three levels: continental level, national level and research institution level. Whatever the level, the factors that have influenced IP regimes and practices can be categorized into "push" and "pull" factors. While there is no standard definition of what constitutes push or pull factors, for the purpose of this research, push factors are considered as those events that are largely exogenous to the policy problem to which policy actors at different levels are likely to respond. On the other hand, pull factors are endogenous factors that affect the strategic and operational priorities of key players and policy brokers. In the majority of cases, push and pull factors act together, although the pull factors are in the end important in determining the efficacy of the reforms adopted and their relevance to the specific institutional and country priorities.

An analysis of the factors influencing IP regimes shows that at the continental and national levels, IP policy regimes have been influenced mainly by push factors especially arising from the global development discourse, bilateral trade programs as well as the interests and activities of international development agencies.[139] However, in addition to push factors, IP regimes and activities at the research institution level are mainly driven by pull factors. As discussed later in this chapter, the two main pull factors in this regard are: the prospects for generating own revenue in the face of reduction in public funding for agricultural research, and peer pressure among scientists, including those from other institutions.

Over the last three decades, there have been wide-ranging reforms in the laws that govern the conduct of agricultural research and innovation in many African countries. The following global policy processes have influenced and shaped the direction and content of agricultural policy reforms on the continent.

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[138] World Trade Organization 1999.

[139] Of all these, the World Intellectual Property Organization (WIPO) has had the most far reaching influence through its development agenda providing wide ranging technical and capacity building support to most African countries.

### 3.4.1 The Impact of Global Trade Negotiations and Global Trade Rules on Intellectual Property Rights

Generally, agricultural policies and laws in many countries gained prominence during the post-independence area. The bulk of these laws were mainly concerned with agricultural marketing, control of pests and diseases and in general the development of the agricultural sector. Until the 1980s, there was hardly any agricultural legislation directly dealing with intellectual property.

At the beginning of the 1980s, the World Bank and the International Monetary Fund (IMF) introduced the structural adjustment programs (SAPs) - a package of monetary and fiscal policy reforms designed to restructure many African economies. The resulting reduction in public expenditure was a major blow to agricultural research and agricultural research institutions that had hitherto relied almost entirely on public funding. The recognition of the apparent failure of the SAPs and their devastating negative impact on agricultural research and development coincided with the Uruguay Round of Trade Negotiations spanning the late 1980s and the first part of the 1990s. Central to the Uruguay Round were the negotiations for global agreements on Intellectual Property Rights[140] and agriculture.[141]

The majority of African countries were exempted from the immediate implementation of the various agreements including TRIPs. The TRIPs Agreement established a global narrative that has had an enduring influence on the development of regional and national policies on intellectual property. In particular, the minimum standards of Intellectual Property Rights protection have become the lowest common denominator for IP policy and legislation in all the countries including those that were not required to comply as a result of the flexibility mechanisms of the WTO agreements. However, the TRIPS flexibilities have not been fully incorporated into the draft national IP laws because the policy-makers do not know how to do so[142].

The influence of the WTO agreements has been elevated by a wide range of technical assistance programs of the WTO and bilateral development assistance programs[143] seeking to further the implementation of the Doha Development Agenda.[144] For example, on the part of the WTO, the Joint Integrated Technical Assistance Programme (JITAP) included a major component on realigning national IP policy and legislation with the TRIPs Agreement.[145]

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140 WTO 1999. Annex 1C, p. 321.

141 See Agreement on Agriculture, Ibid, p. 33.

142 Hasunira, 2011, p.24.

143 The United States Agency for International Development (USAID) particularly invested extensively in providing bilateral support for the reform of intellectual property laws in a number of countries. In Africa, the African Growth and Opportunity Act (2000) made reform of intellectual property laws a precondition for accessing market opportunities in the United States.

144 The Doha Round of Multilateral Trade Negotiations, also known as the Doha Development Agenda was launched in Doha, Qatar in November 2001.

145 JITAP countries include: Uganda, Kenya, Tanzania, Benin, Tunisia, Ghana, Burkina Faso, Cote d I'voire, Cameron, Mali, Mauritius, Senegal, Botswana, Malawi, Mozambique and Zambia.

### 3.4.2 The Global Trade Development Agenda and the Millennium Development Goals (MDGs)

The second major factor shaping the development of IP regimes is the "global development agenda" based on the in-built agenda[146] as the underlying narrative of the last two decades. This global development agenda is epitomized in the adoption of the Millennium Development Goals (MDGs) in May 2000[147] and the launching of the Doha Round of Trade Negotiations. The skepticism over the efficacy of market-based instruments and a rules-based global trading system to deliver equitable development globally has been at the centre of this development agenda. In particular, setting of global development targets on eradicating poverty (MDG 1) reducing child (under-five and infant) mortality (MDG 4) and reducing maternal mortality (MDG 5)[148] implied a new major focus on how to transform the agricultural sectors of the developing world and more especially in Sub-Saharan Africa. As a consequence, this decade has seen the highest concentration of international development assistance towards supporting and reforming the agricultural sectors of many countries in the sub-region. These reforms include the reform of intellectual property laws as part of a strategy to incentivize innovators and holders of agricultural technologies needed to confront major technological constraints facing African agriculture.

### 3.4.3 The Development Agenda of the World Intellectual Property Organization (WIPO)

Another important global process that has significantly shaped the debate and general awareness of IP at the national level is the current global discourse on the development agenda of WIPO. As the world's leading institution on Intellectual Property Rights, WIPO has far-reaching influence on national IP policies mainly achieved through its capacity building programs.[149] Among its goals, WIPO seeks to facilitate the use of IP for development by (i) facilitating the development of "modern and balanced" IP systems in developing countries, and (ii) promoting the use of IP to improve the business environment, encourage innovation, creativity and transfer of technology.[150] In this regard, WIPO provides a wide range of services to the member countries including (i) legislative assistance and advice, (ii) building IP infrastructure and policy making capacity and (iii) development of national and institutional IP policies.[151]

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146 For example, the TRIPS Agreement mandated the review of the implementation of the agreement after January 1, 2000.

147 For a concise look at the MDGs, see Hulme, David 2009.

148 See <http://www.un.org/millenniumgoals/> (accessed on 1 July 2011).

149 WIPO has a membership of 184 members (138 developing countries, including 49 Least Developed Countries (LDCs) and all African countries are members) and administers a total of 24 in global and regional IP treaties. The WIPO Development Agenda was adopted by the WIPO General Assembly in September 2008. The Agenda contains a set of recommendations that seek to facilitate the mainstreaming of development considerations into the work of WIPO, targeting specifically, activities related to technical assistance and norm-setting.

150 See <http://www.un.org/Pubs/ourlives/wipo.htm>(accessed on 1 July 2011).

151 See <http://www.wipo.int/ip-development/en/agenda/> (accessed on 1 July 2011).

Although it is suggested that the programs of WIPO are demand-driven, it is tenable to assert that this principle is the modern development mantra that is generally meaningless for countries that look to institutions such as WIPO for financial support and technical assistance. In effect, it can be argued that in many ways, WIPO drives the policy and legislative agenda on intellectual property in the countries where it is active and especially those of Africa.

### 3.4.4 The Global Discourse on Access to Genetic Resources

The current trends in the IP policy discourse and more especially with regard to agriculture have also been partly influenced by the global discourse on plant genetic resources. The debate on genetic resources in general and genetic resources for food and agriculture in particular can be traced back to the early 1980s. The general debate was given political impetus by the work of the World Commission on Environment and Development (WCED). The Commission was established by the United Nations General Assembly in 1983 and completed its work with the publication of its report – Our Common Future – in 1987.[152] Following on the recommendations of the Commission, the Convention on Biological Diversity (CBD) adopted at the United Nations Conference on Environment and Development (UNCED) contained specific international obligations on access to genetic resources and benefit sharing,[153] and access to and transfer of technology.[154] In particular, article 16 of the CBD obliged contracting parties to the convention to take legislative measures to ensure that technologies "that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources," including those protected by patents and other Intellectual Property Rights, are accessed on "mutually agreed terms, and respecting the IPRs."

It is important to recognize that pre-CBD germplasm collections mainly covering Plant Genetic Resources for Food and Agriculture (PGRFA) were excluded from the scope of the convention and a separate negotiation track on the governance of this collection was pursued through the Food and Agriculture Organization (FAO) of the United Nations, stretching backwards to the adoption of the International Undertaking on Plant Genetic Resources for Food and Agriculture in 1983.[155] This track of the negotiations was concluded with the adoption in 2001 and the coming into force in 2004 of the International Treaty on Plant Genetic Resources for Food and Agriculture (International Treaty), which is consistent with the principles of the CBD providing some special arrangements for plant genetic resources for food and agriculture as components of total biodiversity, and a regime for multilateral access and benefit sharing for genetic resources of major food and feed crops.[156] In particular, Article 12 of the treaty dealing with facilitated access provides *inter alia* that, "Recipients shall not claim any intellectual property or other rights that limit facilitated access to PGRFA, or their genetic parts or component, in the form received from the Multilateral System."[157] It furthermore requires users of germplasm of the multilateral system to pay a percentage of

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152 WCED 1987.

153 Convention on Biological Diversity, 1992, Article 15.

154 *Ibid.*, Article 16.

155 FAO 1983.

156 For detailed discussion on the International Treaty, see Tumushabe *et al.*

157 International Treaty on Plant Genetic Resources for Food and Agriculture, Article 12.3(d).

their turnover when the commercial variety is not freely available for further use in breeding (as may be the case under patent protection in many jurisdictions).

In many ways, the international debate on plant genetic resources and the perceptions of potential benefits has partly fuelled the current discourse on IP in Africa.[158] Breeders in agricultural research institutions are confronted with uncertainty on how to handle a variety of issues ranging from exchange of germplasm, Material Transfer Agreements (MTAs) and intellectual property. What is clear though is that these debates have raised the level of consciousness about intellectual property hence making IP discussions an issue for debate within and among agricultural research institutions on the continent.

### 3.4.5 Intellectual Property Regimes in the Africa Regional Integration Agenda

The current direction in IP policy in Africa is also heavily influenced by increasing continental and regional integration. Over the last decade, Africa has pursued a robust continental integration agenda. On the political front, the establishment of the African Union (AU) as the new Africa-wide political grouping with a set of new institutions and structures accelerated the momentum towards greater cooperation on the continent. In particular, the adoption of the New Economic Partnership for Africa's Development (NEPAD) has been instrumental in creating a continental framework through which common development objectives are pursued. In the area of agriculture and IPR, two major initiatives are worth noting. First, the Comprehensive Africa Agriculture Development Programme (CAADP) was adopted by the Africa Union in July 2003.[159] The CAADP is a partnership framework for the restoration of agricultural growth and food security in Africa. Its pillar 4 regarding improving agriculture research, technology dissemination and adoption covers efforts towards harmonization of policies including on intellectual property.

Second, the *Africa's Science and Technology Consolidated Plan of Action (CPA)* provides a framework for continent-wide collaboration in the area of science and technology. The CPA, which has its origins in the first African Ministerial Conference held in Johannesburg, South Africa in 2003, "articulates Africa's common objectives and commitment to collective actions to develop and use science and technology for the socio-economic transformation of the continent and its integration into the world economy." Besides capacity building, the two other pillars of the Consolidated Plan of Action focus on knowledge production and technological innovation. The CPA considers intellectual property an integral part of the policy environment that needs to be created to enable the CPA's full and accelerated implementation.[160]

One of the major implications of the instruments developed in the pursuit of continental and regional integration is that they multiply the influence of international development agendas on African countries. For example, by participating in these continental programs, institutions such as WIPO exercise considerable influence on the shape and character of key national IP policies and agricultural research priorities.

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158 See article 12 of the International Treaty. For a detailed discussion on the IP provisions of the International Treaty, see Tumushabe *et al.*

159 <http://programmes.comesa.int/index.php?option=com_content&view=article&id=25&Itemid=42&lang=en> (accessed on 1 July 2011).

160 <http://www.nepadst.org/doclibrary/pdfs/ast_cpa_2007.pdf> (accessed on 1 July 2011).

### 3.4.6 Influence of Strategic Philanthropy and Agricultural Development Programs

Besides the range of international and regional policy processes discussed above, the two major factors that have enduring influence on national and institutional IP policies are "strategic philanthropy" and international agricultural funding programs.

Strategic philanthropy is the combined practices through which companies align their charitable activities such as donations and volunteerism with a social issue or cause that supports their economic objectives. For example, in the last decade, global corporate food companies such as Monsanto have adopted a strategy of strategic philanthropy by donating proprietary technology, accompanied by outreach campaigns to ensure the development of national and institutional biosafety and intellectual property regimes that provide protection for these technologies or that open up markets for future commercial ventures. Emerging institutions such as the African Agricultural Technology Foundation (AATF) play the intermediary roles and provide brokerage services between the corporations and the institutions that desire to access these technologies.

The second influencing factor is the international agricultural development programs and partnerships. The most prominent of these include the Centres for International Agricultural Research (CGIAR), and partnership programs such as the Alliance for a Green Revolution in Africa (AGRA). An analysis of some of the partnership and financing agreements reviewed during the course of this study (see Chapter 4) shows that IP provisions are increasingly incorporated in the various research partnerships. These agreements will shape the character and content of IP policies of these research organisations. Indeed, scientists and breeders working with these institutes indicate that the requirements for IP protection has become a more reccurring phenomenon in research partnerships, leading to the need for these organisations to develop their own IP policies.

### 3.4.7 The Influence of Bilateral Assistance Programs

Besides the above multilateral and regional processes, it is important to take note of the influence of the United States on the development of IP policies and legislation on the continent. More than any other country, the United States has for the last two decades executed a deliberate policy and aid programming aimed at "supporting" the development of IP regimes in many African countries. This assistance is often channelled through the United States Agency for International Development (USAID), or through a range of other institutions, programs and legislative initiatives. For example, in 2002 USAID announced the launch of a 10-year program aimed at assisting developing countries "access and manage the tools of modern biotechnology."[161] Through the Collaborative Agriculture Biotechnology Initiative (CABIO), the United States has had tremendous influence by supporting programs aimed at supporting biotechnology applications for developing countries, creating an enabling policy environment for biotechnology which includes reform of IP policy and legislation, human and institutional capacity building in biotechnology, and public outreach especially to policy-makers, political leaders and legislators.

[161] World Food Summit Endorses Biotechnology. Avery DT. Centre for Global Food Issues. August 2002. Available at <http://www.usaid.gov/press/releases/2002/fs020612.html> (accessed on 1 July 2011).

Other programs also combined technical support in biotechnology with biosafety and intellectual property issues, such as the "Program for Biosafety Systems" of the CGIAR, supported largely by USAID, and the Biotechnology East Africa Research Network BioEARN, funded by the Swedish International Development Agency. Through such programs and the biosafety measures in the Cartagena Protocol of the Convention on Biological Diversity, biotechnology became an important vehicle for tabling IPRs.

Besides specific bilateral development programs, the United States in 2000 amended its trade and development legislation to provide for a new trade policy towards Africa. The amendment, also referred to as the African Growth and Opportunities Act (AGOA)[162] authorizes the President of the United States to designate an African country as eligible to access trade and other preferences under the Act if "the President determines that the country has established, or is making continual progress toward establishing the elimination of barriers to United States trade and investment, including by the protection of intellectual property."[163]

### 3.4.8 Conclusion

The impact of IP on access to agricultural technologies by resource-poor farmers and the attainment of the relevant MDG targets, therefore, ought to be understood from the context of the push factors that are informing and shaping the development of national IP policies. On the one hand, international development efforts are helping channel much-needed financial and other resources to agriculture R&D activities that may increase the range of technological products available to farmers in the form of new varieties of seeds. On the other hand, the push towards increased IP protection could undermine the freedom of access to both the tools for enhancing agricultural research as well as actual access to new seed varieties.

## 3.5 Further Developments in Intellectual Property Policies in Uganda

Intellectual property protection is not an end in itself. Rather, intellectual property is an instrument that has to be harnessed to achieve clearly defined development objectives. The utility of IP can therefore only be felt if a country focuses on how to harness this instrument to achieve clearly defined development objectives such as fostering domestic R&D capacity, technology and innovation capacity, promoting foreign direct investment, fostering the acquisition of foreign technology or inducing local manufacturing capabilities. A meaningful IP policy discourse therefore ought to be anchored in the overall development discourse of the country. In the context of MDG 1c, such discourse ought to be anchored in the overall policy to ensure availability and access to new agricultural technologies by resource-poor farmers.

However, the on-going IP policy process in Uganda is largely anchored within the global discourse regarding compliance with the World Trade Organization agreements and focuses through a number of international assistance activities quite a lot on the biotechnology debate. Indeed, across the continent, the debate on national IP policy is largely informed by

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[162] <http://www.agoa.gov/build/groups/public/@agoa_main/documents/webcontent/agoa_main_002118.pdf> (accessed on 1 July 2011). Adopted by the 106th Session of the Congress of the United States, January 2000.

[163] AGOA. Section 104((a)(1)(C)(ii) (19 USC 3703(a)(1(C)(ii)).

the traditional notions that espouse intellectual property as being essential in stimulating innovation, facilitating the transfer of technology and attracting FDIs.[164] Approached from this standpoint, securing the protection of IP incentivizes innovators to create new knowledge and products and hence the public benefits from such protection.

Generally, there is currently no explicit written policy on intellectual property in Uganda. The elements of the policy can therefore only be discerned from a wide range of policy instruments and legislation processes dating back to the early 1990s when Uganda adopted a series of legal reforms covering investment, science and technology and patents. For most of the 1990s, these legal instruments provided the overall policy and legal framework for IP in Uganda. As discussed earlier, the main thrust of these instruments was biased towards IP protection and less on harnessing IP for stimulating domestic innovation capacity. While these instruments were not specific to agriculture, the Investment Code Act particularly provided for agriculture as one of the sectors eligible for investment incentives established under the Act.

However, for the same push factors described above, a more intensive debate in intellectual property policy has been going on for the last decade. IP policy discussions have taken place along three main tracks: the biotechnology policy framework in the context of the Cartagena Protocol on Biosafety[165], the reform of commercial laws, and compliance with the Doha Development Agenda of the WTO.

### 3.5.1 Biotechnology and IPRs

The biotechnology policy track is managed by the National Council for Science and Technology.[166] The process of formulating a national policy on biotechnology gained momentum around 2000 with the adoption of the Cartagena Protocol on Biosafety.[167] Among other things, the Protocol obliges the parties to the Convention on Biological Diversity to develop and adopt national policy frameworks for biosafety. The first draft of the national policy was published in 2004[168] and the final draft in 2007.[169] The 2007 draft policy provides that "a strong emphasis will be placed on biotechnology and biosafety R&D in priority areas of food and agriculture, health, industry, environment and natural resources development." The policy whose formulation was supported under the USAID's Program for Biosafety Systems (PBS) was adopted by the cabinet in 2008.

Government also adopted the National Science, Technology and Innovation Policy under the Uganda National Council for Science and Technology. Among other things, and without any specific reference to smallholder agriculture, the policy provides that government shall facilitate and encourage science and technology innovation through protection and use of intellectual property.[170]

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164 Tumushabe & R. Naluwairo 2005, p.1.

165 United Nations 2000.

166 The Uganda National Council for Science and Technology is established under the Uganda National Council for Science and Technology Act, Cap 209. Revised Edition of the Laws of Uganda, 2000.

167 Cartagena Protocol on Biosafety to the Convention on Biological Diversity, Montreal, 2000.

168 Republic of Uganda 2004.

169 Republic of Uganda 2007.

170 Republic of Uganda 2009.

### 3.5.2 Reform of Commercial Laws

The commercial laws reform track is managed by the Uganda Law Reform Commission and the Uganda Registration Services Bureau (URSB). One of the major legislative efforts under this track has been the development of a bill on plant variety protection.[171] While this legislation process provides an opportunity for effectively balancing the rights of breeders and farmers, aspects of farmers' rights have been removed from the advanced draft of the legislation.[172]This denies the central role and importance of the informal seed system in the country. A totally different approach can be found in Ethiopia, where an IP policy is being developed that recognizes and facilitates the operation of different seed systems side by side (see Box II-4).

**Box II-4:** ***Options for IPRs in the Seed Sector – Examples from Ethiopia***

*During the course of this project, a team member was involved in a process that should lead to a balanced IP protection of plant breeding innovations in Ethiopia. The government of Ethiopia intends to provide IP protection in order to stimulate the commercial sub-sectors in agriculture, while preparing for WTO membership. At the same time, Ethiopia puts value to its position as a centre of diversity for a number of crops, and recognizes the needs and rights of the majority of (smallholder) farmers.*

*The country has adopted the concept of integrated seed system development, recognizing that different seed systems operate side by side. At the commercial extreme is the sector producing flowers for export, using planting materials under a license with foreign commercial breeders. For this, full IP protection at the level of the IPRs in the importing countries (mainly Europe) is required to optimally support the sector. This means that multiplication by farmers without the consent of the breeder should be disallowed. At the other extreme are the millions of smallholder farmers, using their own landraces, modern varieties that they accessed from neighbours and kin, and mixtures of both. For this sector, farmers' rights, particularly those in relation to the saving, exchanging and local selling of seed should be fully recognized, including the use, exchange and non-commercial local sales of seed. Without such right, seed security would be severely challenged. A draft amendment to the Plant Breeder's Rights Proclamation is under way specifying three levels of rights.*

*The country's patent law excludes the protection of plant varieties, which is interpreted as including patents on plants and genes that express at the level of the plant variety. Ethiopia is also amending its Seed Proclamation in order to create options to avoid limitations to the farmers' rights through compulsory seed certification.*

The WTO accorded Least Development Countries (LDCs), the category in which many African countries including Uganda fall, differential treatment - they have received more time to implement the TRIPs Agreement (except for national and most-favored-nation treatment until January 1, 2006). Pursuant to this extension, Government of Uganda applied and received funds under the WTO technical assistance program to develop a comprehensive national IP policy. A comprehensive background study was undertaken to provide a foundation for the formulation of the policy.[173] Sources within the Registration Services

171 See Annex 1 to the study and reform on plant variety protection law.

172 Naluwairo 2010, p. 4.

173 SAANA Consulting and ICTSD 2007.

Bureau indicated during the course of this study that neither WTO nor the government of Uganda have been able to allocate funds to take this process forward.[174]

## 3.6 Conclusions

*The IP framework has developed largely by push factors without specific reference to the needs of resource-poor farmers and food security*.
The IP framework has arisen from colonial rules. Its development has further developed driven by push factors in the form of membership of regional and international organisations and bilateral assistance programs along the lines of international developments without specific reference to the needs of Ugandan innovators and technology users and definitely no specific focus on resource-poor farmers and food security.

*The legal and institutional landscape in Uganda is scattered with limited coordination, and each organization with its own (foreign) partners that may bring in specific ideas.*
These push factors also explain why there are multiple policy processes handled by different agencies and at different times. While issues of agriculture are clearly conspicuous in the biotechnology policy debate, they are neither apparent in the commercial law reform track or the WTO compliance track. This may also be the reason why various law proposals have been on the table - ranging from adoption of the main components of the African Union Model Law, to a more recent proposal to frame a UPOV-like system - but none have been accepted and implemented so far.

*The potential implication is that future IP policy reforms along these tracks may adversely affect the development of and access to new seed varieties and undermine the attainment of the relevant MDG goals.*
It is therefore important that the IP policy formulation process be more streamlined and brought under the ambit of one government agency such as the Uganda National Council for Science and Technology. Alternative, multi-stakeholder policy forums require a stronger development-oriented analytical work that goes beyond mere compliance requirements with the obligations established under the WTO and WIPO international instruments. The flexibilities of TRIPS are insufficiently used.

[174] Interview with a URSB official in February 2011.

# CHAPTER 4 IP POLICIES AND PRACTICES AT AFRICAN AGRICULTURAL RESEARCH ORGANIZATIONS

*Godber Tumushabe & Julian Barungi*

**Abstract**
Having examined the factors that influence the development of IP in Africa, it is important to examine the content and character of IP policies that have been developed to date. This chapter addresses three key issues that are essential to the understanding of IP policy trends on the continent. First, it examines the current and emerging perception on IP among African research managers and scientists. Second, we analyse the content of IP policies of African research institutions based on the IP instruments that have been developed by selected African universities and agricultural research organizations. Finally, we examine the IP content of selected research funding partnerships between African agricultural research institutions and international agricultural research centres and financing agencies. Two main conclusions emerge from this analysis. First, there is a growing trend towards formulating institutional policies on IP. Second, there is generally no consistency in the manner in which international research partnership agreements approach the issue of IP. Consequently, this apparent gap provides a tremendous opportunity for African agricultural research institutions to shape the content of institutional IP policies to ensure that they reflect their research for public goods mandate.

## 4.1 Introduction

The increasing attention on IP by African countries is also apparent at the level of African research institutions and some of the key actors that support the work of these institutions. The majority of these institutions are not only changing and streamlining their IP policies, their practices and the perceptions of individual scientists and practitioners within them are also changing. Changes in institutional IP policies are taking place within at least four different types of institutions. These are: IP policy and administration agencies; national agricultural research institutes; universities; and international institutions providing research support, [175]technology brokerage services[176] or funding.[177] Consequently, the implications of those changes on access to agricultural technology and the attainment of MDG 1c will largely depend on how the mandate of these institutions relates to agriculture.

First, there are fundamental changes taking place in key national IP policy and administration institutions in the majority of African countries. Such institutions include the national councils for science and technology,[178] the IP administration institutions[179] as well as

[175] The main players in this category are the international agricultural research centres that are members of the Consultative Group on International Agricultural Research (CGIAR).

[176] This category includes institutions that have been put in place to facilitate the transfer of proprietary agricultural technologies. The most visible actor in this category is the African Agricultural Technology Foundation (AATF). Available at <http://www.aatf-africa.org/> (accessed on 1 July 2011).

[177] There are a number of organizations (*e.g.* Gates Foundation) and initiatives (*e.g.* AGRA). <http://www.agra-alliance.org/> (accessed on 1 July 2011).

[178] Across the continent, it is the national councils for science and technology that are largely responsible for the development of biotechnology policy.

ministries of trade.[180]The national councils for science and technology are increasingly taking on an active role in creating awareness on IP among scientists and research organizations in their effort to bridge the innovation chasm. For example, the Uganda National Council for Science and Technology has a specialized National IP Advisory Group that advises the Council on how to address issues of IP in research funding agreements.[181]

Intellectual property administration institutions on the other hand are often more concerned with IP examination, IP law enforcement and compliance. As discussed in Chapter 3.3, these are more likely to pursue a WIPO compliant agenda. By the nature of their mandate, they should ensure that their work contributes to the positive impacts on society, which requires institutional leadership and creativity.[182] Finally, as discussed in chapter 3.3, ministries of trade are often more concerned with compliance with the respective WTO agreements and less with the agriculture research and development agenda.

Like national agricultural research institutes and universities, international agricultural research centres engage in extensive agricultural research and innovation work and hold a considerable repository of agricultural technologies. Consequently, their internal policies on IP may have implications for the flow of relevant technologies to the national agricultural research systems and therefore impact access to new seed varieties by poor and smallholder farmers.

While major national IP policy debates are taking place within the IP policy and administration institutions such as the councils for science and technology, trade ministries and IP offices or bureau, the impact is being felt and translated into practice at the level of research institutions.

In the following part of this chapter therefore, we examine the perceptions of IP managers across the continent and how these perceptions shape the character and content of emerging institutional IP policies. Since formal institutional IP policies are largely being formulated, interviews were conducted with a number of directors of research institutions to get their perceptions on the subject. The bulk of these interviews were conducted during the Fifth General Assembly of the Forum for Agricultural Research in Africa (FARA).[183] Additional interviews were conducted with agricultural research mangers and selected international development partners in Uganda and Kenya. These interviews revealed a wide range of factors and perceptions are informing IP policies at the institutional level and among individual scientists.

The discussion in this chapter is presented in four sections. After this introduction, the next section (4.2) analyzes the factors shaping the development of IP policies at the level of African agricultural research institutions. This discussion is informed by the analysis of

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179 These are institutions that are largely charged with the administration of IP including compliance and law enforcement. Examples include the Kenya Industrial Property Institute (KIPI) or the Uganda Registration Services Bureau (URSB). These agencies mainly work with or receive technical assistance from the World Intellectual Property Organization (WIPO).

180 In all the cases, ministries of trade are responsible for the implementation of the World Trade Organization including the TRIPS agreement.

181 Interview with an official of the Uganda National Council for Science and Technology on July 30, 2010. Also see UNCST 2010.

182 For example, within the East African Community (EAC), the Kenya Industrial Property Institute (KIPI) plays a more proactive role in enhancing the use of patented knowledge by scientists.

183 The meeting took place in Burkina Faso, July 19-24, 2010.

existing institutional policies as well as the perceptions of researchers and agricultural research managers. Section 4.3 analyzes the key features of emerging institutional IP policies and the IP practices of these institutions. Finally, 4.4 discusses the impact of agricultural research funding partnerships on IP policies of agricultural research institutions and their implications to the attainment of MDG 1c.

## 4.2 Factors Shaping IP Policies of Agricultural Research Institutions and Perceptions of Researchers and Research Managers.

Agricultural research institutes dominate the realm of public research in Africa. Across Africa, national research organizations (generally referred to as NAROs) are the major players next to universities in national agricultural research systems (NARS). Besides the external influences discussed in Chapter 3.3 above, there are wide-ranging considerations within agricultural research institutions and among the agricultural research community that are defining the trends in IP policy within the agricultural sector.

### 4.2.1 Generally Diverse Awareness of IP

In general, there is diverse awareness of IP and what IP policies should be intended to achieve. It is recognized that in many research organizations at the national level, awareness about IP is generally low. The dean of the University of Butare (Rwanda) indicated that his organization is fully paid by the government and that there have not been any discussions about IPRs yet. Similar positions were expressed by his colleague from the research institute in neighbouring Burundi, who however recognizes that it may become an issue in the future. The acting director of the Agricultural Research Corporation in Sudan mentioned that there are no Plant Breeder's Rights in his country and that he has no knowledge of patents, but that Bt-cotton is being introduced.

It is therefore clear that there is a category of research directors who do not see any direct link between their research work, IP and access to new seed varieties by resource-poor farmers, probably because IPRs are not yet fully operational in their countries. However, several of these research managers expressed interest in learning more about the role and the potential implications of IP on their mandate to provide public goods and services. This presents a major opportunity to ensure that the future development of institutional IP policies is properly aligned to the objective of facilitating access to new seed varieties and the attainment of the MDG 1 targets.

### 4.2.2 Perceived Benefits from IP

African agricultural research institutions face a multiplicity of challenges which in many cases conflict with their public research mandate. In particular, public funding for these institutions has either been declining[184] or has remained unchanged even when the need for agricultural research has continued to expand in the face of major problems such as new pests and

[184] For example, budgetary allocations for agricultural research and technology in Uganda declined from 7% of the total funding for the Plan for Modernization of Agriculture (PMA) during the FY2005/06 to 4% during the FY2007/08. See Lukwago 2011.

diseases, drought and climate change as well as post-harvest losses. In light of these major constraints, the respondents who had some knowledge of IP see it particularly as a potential opportunity for both the research institutes as well as the scientists. The benefits are perceived to accrue in two ways.

First, it is hoped that revenues accruing from the licensing of IP could help boost the productivity and innovation capacity of scientists, as they will be rewarded for their innovation work. This perception is already reflected in the royalty or revenue sharing structure that is being incorporated in some of the emerging institutional IP policies as discussed later in this Chapter. For example, one of the leading scientists at Makerere's Faculty of Agriculture observed that with the institutionalization of IP, researchers will be able to "demand payment for their brains" clearly reflecting the fact that scientists continue to be underpaid in spite of the perceived commercial value of their innovations.[185]

Secondly, given the continuously dwindling public funding for agriculture research in Africa, a number of respondents thought that IP could become a potential source of revenue for the institutes. There are growing examples where national laws require IP protection for new plant varieties and the generation of revenue from licensing activities. For example, according to the director of the South African Agricultural Research Council, protection of plant varieties by public organizations is a requirement under the South African law. Accordingly, the council has generated approximately 50 million rand, which constitutes about 5% of the Council's budget. The legislation which is based on the 1978 Act of UPOV also allows farmer-to-farmer exchange of seed which the council considers essential for the transfer of improved varieties to farmers. This arrangement with a strong farmers' privilege and yet a substantial income from royalties may show a good example of fine-tuning IP laws to local needs.

For a few research managers, the protection of IP is a financial lifeline for dwindling budgets arising out of cutbacks in public financing. The Field Crops Research Institute of Egypt provides varieties to the public "Central Administration for Seed" and a large number of commercial seed companies. Royalties based on Plant Breeder's Rights are paid on the basis of the quantities of seed produced, assessed through the certification system. This brings in over 50% of the annual budget of the institute without which it would not be able to perform. There are yet no cases that patent protected biotechnologies (from the Agricultural Genetic Engineering Research Institute) have reached the practical plant breeding work. The director claims that the institute has not yet assessed the possible consequences of dealing with such rights. Kenyan Agricultural Research Institute (KARI) has a commitment to grow towards 20% self-financing. IPRs are considered an important tool to generate income. However, this should not imply a reduced focus on poverty reduction. At the Institute of Environment and Agriculture Research (INERA) in Burkina Faso,[186] all varieties are protected through Plant Breeders Rights (PBRs). However, the director is of the view that farmer-to-farmer exchange of seed is essential from a development point of view. He further observed that smallholder farmers are also reached through subsidies on seed. The University of Malawi would welcome IPRs to create a flow of revenue that could improve the working environment of scientists and breeders, but at the same time it is regarded that IPRs, due to the secrecy that working

[185] Interview with research scientists and IP managers at Makerere University Faculty of Agriculture, July 30, 2010.

[186] For details, see Kabore, Sawadogo, S. Available at <http://www.cas-ip.org/projects/npi/npi-publications/> (accessed on March 2, 2011).

towards patents requires, may reduce the interaction among researchers (and students) which is essential for the university.

Thirdly, there are widespread perceptions that IP could provide a basis or mechanism for building public-private partnerships that could help move new technologies into the market and hence make them accessible by farmers. For example, the Dean of the Faculty of Science and Agriculture at the University of Kwazulu Natal (South Africa) also indicated that under a new policy, a staff of the Ministry of Science and Technology would be posted to the university to implement the IP protection process as well as freedom-to-operate procedures. A scientist at Makerere University reported that negotiations for a public-private partnership for the release of a new soybean variety were going on at the time of conducting this study.

The directors of Institut Sénégalais des Recherches Agricoles **(***ISRA***)-**Senegal and the National Agriculture Research Institute (NARI) in the Gambia independently mention that a general idea for the future is to develop more public-private partnerships in agricultural research, and that IPR could be a tool in managing such development, notably in horticulture. However, both mention the dilemmas of at the same time meeting the need for national food production, mainly by resource-poor farmers. They see challenges in merging the different goals and their translation into IP policies.

### 4.2.3 Pursuing IP Protection versus Public Goods

One of the major issues confronting agricultural research institutions is the potential or perceived conflict between IP protection and the public goods nature of agricultural research. The fundamental question is whether or not IP could shift the focus of public research institutions from developing crop varieties for smallholder agriculture such as beans, cassava and others and focus on high value commercial crops such as maize. Some of the respondents for this study indicated that the concept of public goods would remain central to the spirit of public agricultural research in their institutions whether there was IP or not. For example, the deputy director of the Ethiopian Institute for Agricultural Research (EIAR) in Ethiopia indicates that an IP policy was being developed but that it would not change the principle that the institute has to produce public goods. Current practice is that patents (the Plant Breeder's Rights law is not yet implemented) are applied for only if there is a clear indication that without protection a problem will arise in the innovation chain to product development and use.

The director of the Department of Agricultural Research in Lesotho indicates that his main task is to contribute to poverty reduction and that commercial farming is largely absent. Even though his country is an observer in UPOV, IPRs are not particularly relevant since there are few real breeding activities, but only screening of public varieties from the CGIAR and neighbouring South Africa. The spokesman of the Nigerian Agricultural Research Council confirmed the importance of IPRs which will be included in the strategic plan the council was developing. Finally, the director of programs at the National Centre for Scientific Research (CNRS) in Côte d'Ivoire indicated that the public role of CNRS prevails over any considerations for IP protection. Knowledge and varieties are protected to avoid that others claim inventorship (defensive). Technologies are available for free for anyone in the country. However, if outsiders wish to use them, terms will be negotiated. This could involve the exchange of genetic resources with foreign organisations, or sharing of benefits with the private sector.

The perceptions of African agricultural research managers discussed above furthermore point to four critical issues that confront breeders and public research institutions, in Africa. How these issues are addressed may affect access to new seed varieties especially by poor and smallholder farmers and shape the role of IP in the pursuit of MDG 1c. These issues are: availability of intellectual property protection; ownership of intellectual property; institutional capacity for IP management, and access to proprietary technologies owned by foreigners.

At the national level, these issues are answered by way of looking at national policy and legislation governing intellectual property (Chapter 3). At the level of national agricultural research institutions, an examination of formal and informal policies of the respective institutions can provide some insights on how these issues are being addressed and particularly how the approaches being taken affect resource-poor farmers and the attainment of MDG 1c. These aspects are dealt with in the following section

## 4.3 Key Features of IP Policies and Practices of African Agricultural Research Institutions

Public agricultural research institutions in Africa are mainly comprised of national agricultural research organizations and universities. The majority of these institutions receive public funds to undertake research or get funded largely by donors. However, recent trends show that these institutions are increasingly IP partly as a strategy to commercialize the technologies they develop so that they can generate their own revenue to fund research and motivate scientists. Yet, the commercialization of scientific knowledge and innovation could have far reaching consequences for access to new agricultural innovations by smallholder farmers.

It is also evidence that, with few exceptions, universities rather than national agricultural research institutes are at the forefront of developing institutional IP policies. Much of this discussion in this part of the paper therefore analyzes the IP policies of selected universities across the continent. An analysis of the available written policy documents for these institutions clear show the following common features across the board.

### 4.3.1 IP Awareness is Growing

There is general acceptance that awareness of IP among African scientists and African research institutions is still very low. Heads of research institutions interviewed for this study were unanimous both on the importance of IP but also on the fact that there is much more work to be done to raise awareness on IP issues. In the face of constrained budgets, the work of raising awareness on IP is mainly championed by research coordination institutions or national IP institutions often with the support of bilateral donors and the World Intellectual Property Organization (WIPO). In Uganda for example, the Uganda National Council for Science and Technology (UNCST) and the Law Reform Commission (LRC) are some of the key institutions that focus on raising awareness on IP mainly through stakeholder workshops. A review of the Uganda workshop reports particularly reveal that the workshops are mainly focused on traditional IP such as patents and there seem to be less emphasis and less content on Plant Breeders' Rights.

**Box II-5*: Scope of IP in Institutional IP Policies***

- Patent;
- Trade Mark and Service Mark;
- Copy rights and Neighboring rights;
- Industrial Design;
- Utility Model;
- New Plant Varieties;
- Trade Secrets and Know how;
- Integrated circuits or layout designs;
- Geographical Indications;
- Tangible Research Property (TRP) and genetic resources and;
- Traditional Knowledge and Folklore.

### 4.3.2 Institutions are Beginning to Put in Place New Policies

Across the continent, national institutions are adopting written policies and creating specialized offices to provide guidance on intellectual property. The process of developing these policies has accelerated mostly over the last 10 years. Moi University adopted its research policy in 2004.[187] The University of Nairobi adopted its IP policy in 2006.[188] Makerere University adopted its policy in 2008 while the University of Zambia Research Policy and IPR was adopted in 2009.[189] For example, University of Nairobi and Kenyatta University in Kenya, Makerere University in Uganda and University of Zambia in Zambia have appointed IP officers in the last 5 years. Most importantly, these and many other universities developed and adopted formal policies on intellectual property addressing issues of IP ownership, institutions for managing IP, sharing of royalties and other related matters. In several countries, the research institutes are less advanced in framing IP policies.

### 4.3.3 Availability of Intellectual Property

Traditionally, African universities and research institutions did not have any policies on the availability of intellectual property. There may have been some awareness of the existence of copyright, but agricultural innovations like all other innovations were treated as public goods that were freely available to the public. There may have been some awareness of the existence of copyright. This approach was also reinforced by the fact that the bulk of research was funded by public funds. The absence of clarity on the availability of IP was also compounded by the absence of awareness among leaders of research institutions. However, this is now being addressed through the emerging institutional policies. By adopting formal institutional policies, the institutions are making it clear that they intend to take advantage of innovation activities taking place within these institutions. The scope of the IP available is generally consistent and the bulk of the institutional policies reviewed restate the IPs highlighted in Box II-5.

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187 Moi University 2004.

188 See <http://www5.uonbi.ac.ke/ip/?=node/35> (accessed on 1 July 2011).

189 University of Zambia 2009.

### 4.3.4 Ownership of Intellectual Property

The emerging institutional policies also deal with the ownership of intellectual property developed during the course of research. Research undertaken at public universities and public agriculture R&D institutions raise fundamental issues regarding IP ownership. First, the research is undertaken by individual scientists who may claim ownership of their innovations or creations. However, these scientists are employed by public research agencies and the bulk of their research work is publicly funded both by governments and international development partners. There is therefore the critical issue of striking a balance between creating incentives for innovation while preserving access to new technologies by the public.

While there are variations, there is some consistency in the IP policies of the universities that were reviewed as part of this study. With very few exceptions, the general trend is that all IP created by scientists working with the universities in the course of their duties and with university funding is owned by the university. A particularly unique approach is found in the Ugandan legislation establishing the framework for agricultural research in the country. The National Agricultural Research Act[190] vests all intellectual property arising from publicly funded research into the National Research Organization. This particular position creates a fairly complex legal situation since any changes in such vesting of rights would require parliamentary or ministerial approval.

**Box II-6:** ***Ownership of IP From Publicly Funded Research in Uganda***

*PART VI: Discoveries, Inventions, and Improvements by Agricultural Research Services Providers*[191]
*39. Rights of Patents, Inventions, etc.:*
*(1) All rights of patent in discoveries, inventions and improvements on proprietary inputs both technological and material, transformational systems, selectable markers, promoters, genetic research including diagnostic probes, shall vest in the organization in cases of agricultural research from public funds.*
*(2) Subject to subsection (1), the rights in all discoveries and innovations and in all improvements in respect of processes, apparatus and machinery*
*(a) persons assisting the organization with any investigation or research shall vest in the organization, or*
*(b) Persons to whom bursaries or grants-in-aid have been granted by the organisation shall vest in the organization.*
*(3) For the purpose of this section, the Intellectual Property Rights are limited to tools and methods used in agricultural research.*
*(4) The organization may make discoveries, inventions and improvements referred to in subsection (2) available for use in the public interest subject to such conditions or the payment of such fees or royalties as the organization may determine.*
*(5) Where any discovery, invention or improvement is vested in the organization under subsection (1), the organization may award to the person responsible for the discovery, invention or improvement such bonus as agreed, or make provision for financial participation by that person in the profits derived from the discovery, invention or improvement to such extent as the organization may determine, after consultation with the minister and in accordance with existing laws relating to intellectual property.*

190 Republic of Uganda 2005.

191 *Ibid.*

*(6) The organization or an agricultural research provider may apply for a patent in respect of any discovery, invention or improvement referred to in subsection (1), and shall for the purpose of Patents Act and Plant Variety Protection Act be regarded as the assignee of the discoverer or inventor in question.*
*(7) The minister in consultation with the council[192] shall prescribe by regulations the manner of protecting intellectual property, innovations, improvements and inventions arising out of agricultural research.*

Besides ownership rights, the emerging policies also provide for a set of non-monetary incentives aimed at stimulating individual creativity and innovation. In particular, the Moi University Research Policy 2004 provides for recognition of innovators that excel in technology transfer by various awards.

### 4.3.5 Management of Intellectual Property

Another common element of the emerging institutional IP policies is the creation of IP management structures at the respective institutions. The institutions that are being created are designed to address two management deficiencies. The first set of institutions focus on the internal management of IP with emphasis on general IP management, coordination of IP activities, negotiating and managing research agreements, development of guidelines and generally handling IP filings and related procedures. This category of institutions includes intellectual property offices (IPOs) and intellectual property advisory committees. The second category of institutions is those that are designed to focus on the transfer and commercialization of the technology. While it is common to have this second set of institutions embedded within the IP offices, they nevertheless put their emphasis on downstream IP services focusing on moving innovations into the market. These institutions include the technology transfer offices (TTO) and business incubation units.[193]

### 4.3.6 Royalty Payments and Sharing of Benefits

Emerging policies also address one of the most pressing issues regarding monetary incentives for researchers in public institutions. The question that has often dodged public and institutional policy is how to ensure that scientists in public research institutes derive a monetary benefit from their intellectual creations. In this regard, most of the policies that are being adopted by universities and NARS provide a mechanism by which royalties from the commercialization of IP can be shared among the main actors. An analysis of the provisions governing the distribution of royalties shows attempts to ensure that a wide range of stakeholders in the R&D process benefit from the commercialization of IP. The most comprehensive checklist of stakeholders to benefit from commercialization of IP is contained in the University of Zambia IP policy which lists at least seven beneficiaries (Box II-7). The other policies mainly provide for sharing of royalties between the inventors, the university and the host department.

[192] National Agricultural Research Council established under section 5 of the Act.

[193] For example, Moi University Holdings Ltd at Moi University.

**Box II-7: *Revenue Distribution from Commercialized Intellectual Property Rights***

*12.2.1 Gross Income shall be understood as funds obtained from commercialization of an Intellectual Property Right. Net Income shall be understood as Gross Income less expenses incurred by the University of Zambia for Intellectual Property Rights processing, protection, maintenance, licensing or Assignment of IPRs.*

*12.2.2 Where an invention made by an employee of the University of Zambia is commercialized, the net income shall be distributed to the following:*

*(i) 45% ----------to the Inventor or creator;*
*(ii) 10% ----------to the IP Fund of the University of Zambia;*
*(iii) 10% ----------to the Inventor's research or creator's project;*
*(iv) 5% ----------to the Inventor's or creators' departmental infrastructure;*
*(v) 5% ----------to the Faculty infrastructure;*
*(vi) 10% ----------to the Intellectual Property Management Unit, and*
*(vii) 15% ----------to the University research project fund (Central Administration)*
*Source: The University of Zambia (2009). Research Policy and Intellectual Property Rights. Directorate of Research and Graduate Studies, June 2009 (p. 62)*

### 4.3.7 Conclusion

The foregoing analysis shows a growing movement in institutions and scientists that see intellectual property as one way of addressing some of the financial problems facing public agricultural research institutions across the continent. As already alluded to, one of the dominant features of the emerging institutional IP policies is the sharing of revenues or royalties arising out of commercialization of IP. The link between these policies and the mandate of public agricultural research institutions to make the products of their research available to the public is not very clear or may only be drawn as a matter of inference.

## 4.4 The Impact of International Agricultural Research Centers and Funding Partners on IP Policies of Agricultural Research Institutions

Besides the interests of agricultural research institutions to generate revenue from IP and to motivate scientists, research and financing agreements between national institutions and international research and funding agencies also influence institutional IP policies. The fundamental question may be whether such influence is geared towards the use of IP to attain MDG 1c or whether such influence in fact undermines the pursuit of the MDGs. An analysis of existing research and funding agreements reveal fairly inconsistent trends that do not give a very clear picture.

### 4.4.1 Research Partnership Funding Agreements

To get a better understanding of the current partnerships, a number of research partnerships that provide funding for agriculture R&D were reviewed during the course of this study.

Interviews were also held with key scientists and managers of selected international agricultural research centers.

The analysis of research partnerships and funding agreements shows that increasingly, IP provisions are incorporated in the various research partnerships. For example, one of the agreements between the National Agricultural Research Organization (NARO) of Uganda and the International Institute for Tropical Agriculture (IITA) on small scale cassava processing and vertical integration of the cassava sub-sector in Southern and Eastern Africa contains extensive provisions of IP.[194] The agreement vests the exclusive ownership of "technology and know-how acquired as a result of the project or otherwise emanating from the activities thereunder" in the Common Fund for Commodities (CFC) which provided the funding for the research work under this agreement. Under the agreement, "NARO acknowledges and confirms that it has no rights of whatever nature to the technology and know-how acquired as a result of the project or otherwise emanating from the activities undertaken thereunder" and that it shall keep all such technology and know-how confidential. More curiously, the agreement further provides that "the CFC shall have exclusive right to the publication, in whatever form, of the results and technical outputs of the project" and that "the CFC shall own the copyright to and the revenues accruing from the sale of any publication issued by [CFC]." Any interests by NARO to claim proprietary interests on the technology or the know-how acquired as a result of the project activities are to be negotiated with the CFC in consultation with the FAO and IITA.

In another partnership agreement between the Uganda's National Agricultural Research Organization (NARO) and IITA on sustainable integrated management of whiteflies as pests and vectors of plant viruses in the tropics, NARO commits itself to "furnish IITA with copies of any proposed publication or presentation at least 30 days in advance of such publication or public presentation" in order to avoid improper disclosure of IITA's proprietary information or loss of patent protection through public disclosure.[195]

While these agreements have clearly restrictive provisions that could impact on access to technology by resource-poor farmers, selected agreements that date later than 2006 represent an apparent shift in the nature of IP restrictions imposed through research partnership and financing agreements.[196] For example, in 2006, the Donald Danforth Plant Science Centre (DDPSC) concluded an agreement with the National Crop Research Institute (NaCRRI) of Uganda on Virus Resistant Cassava for Africa-Uganda (VIRCA-Uganda). Among other things, the agreement vests ownership of "any original data or intellectual property generated using Ugandan cassava materials and the analyses produced during the course of work" under this partnership in both NaCRRI and DDPSC. The agreement also encourages NaCRRI to publish results of work generated under the agreement provided that prior written consent of DDPSC is obtained (and that such will not be withheld unreasonably.)

In another 2006 agreement between Natural Resources Institute of the University of Greenwich (NRI) and NaCRRI regarding the dissemination into Uganda and the screening of South American whitefly resistant cassava genotypes, Intellectual Property Rights associated with the research work to be performed under the agreement are subjected to the provisions of the original material transfer agreement (MTA). The IP provisions of the MTA prohibit the

194 NARO 2003.

195 NARO 2005.

196 This shift may be attributed to the increased debate on the role of IP in development and more especially in the context of the WIPO Development Agenda.

acquisition of IP on the material or related information and encourage NaCRRI as the recipient to share the benefits accruing from the use of the material.

In a more recent 2008 agreement between the Association for Strengthening Agricultural Research in Eastern and Central Africa (ASARECA) and Uganda's National Agricultural Research Organisation (NARO) on the establishment of a genetic transformation platform for cassava in Uganda, the parties agreed that all rights, titles and interests in intellectual properties arising from this agreement (including copyright, trademark, patent, computer programs and database rights) produced by NARO or its personnel in conjunction with ASARECA or its personnel shall be assigned jointly to NARO and ASARECA. It is not clear how such joint ownership operates and whether this assists or blocks effective and efficient use of the technologies depends on the 'use' provisions in the agreement.

This shift towards less restriction on IP is also clearly evident in recent agreements regarding research on maize. In 2010, Uganda's NARO concluded partnership agreements with the Alliance for Agricultural Research in Africa (AGRA) and the International Maize and Wheat Improvement Centre (CIMMTY). The agreement with AGRA on the development and dissemination of stress tolerant maize varieties obliges NARO to make the results of the project such as "any written reports, publications of any kind, and any materials of any nature created by NARO regarding the project as a result of or in connection to this grant (collectively, "the materials") available to the public…" The agreement also secures for AGRA "a perpetual, world-wide non-exclusive license to use, reproduce, distribute, display, perform, edit, adapt, create derivative works from and otherwise utilize ……. all materials created by NARO as a result of or in connection to this grant." The series of agreements between NARO and CIMMYT have IP provisions couched along the same lines as the agreement with AGRA. These projects deal with (i) the quality protein maize development and dissemination project, (ii) the drought tolerant maize for Africa project, and (iii) the insect-resistant maize for Africa (conventional resistance) project.

An important exception is the agreement between NARO, Monsanto and the African Agricultural Technology Foundation (AATF) regarding the Water Efficient Maize for Africa (WEMA) Project.[197] This project, which is a joint initiative of AATF, the national agricultural research systems in Kenya, Uganda, Tanzania, Mozambique and South Africa, CIMMYT and Monsanto, seeks to develop and deploy drought-tolerant African maize using conventional breeding, marker-assisted breeding and genetic modification (GM). The objective of the project is to develop and make drought-tolerant maize available royalty free to small-scale farmers in Sub-Saharan Africa.

However, some of the provisions of the WEMA project agreement raise critical issues regarding the potential influence of such agreement on the institutional policies of research institutions, such as NARO on the one hand and access to the technology by smallholder farmers on the other hand. Among other things, under the agreement, Monsanto grants to NARO a non-exclusive, non-transferable license to use Monsanto technology and seed under Monsanto IP rights to conduct testing in Uganda. Secondly, the agreement prohibits NARO from conducting any field tests or maintaining any transformation line without the prior written consent of Monsanto. Thirdly, the agreement provides that "this cooperation is not a grant of a license or other rights to use seed, Corn Technology or Monsanto IP rights in the

[197] For a detailed description of this project, see <http://www.aatf-africa.org/userfiles/WEMA-brief.pdf> (accessed on 1 July 2011).

development of any corn – intended solely to evaluate the performance of Seed and Corn." Finally the agreement further provides that "title to all Seed and Corn and to their germplasm, genes and DNA sequence will remain with Monsanto."

In many ways, this particular case represents the emerging complexity of partnerships between public research organisations and private seed companies such as Monsanto. While other agreements clearly provide the flexibility for public research institutes such as NAROs to use the products of the partnerships to produce public goods, there is no doubt that the agreement involving Monsanto entails wide-ranging restrictions on the deployment of the technology since the agreement allows only the process of evaluation. This implies that any downstream research work including product development and deployment rights will be negotiated separately. At the moment, it is not clear how these restrictions may be reconciled in the policy of NARO as set out in the Agricultural Research Act.

Although this review is based on selected partnership agreements with Ugandan agricultural research organisations, the review clearly reveals a trend where IP provisions are embedded within the agreements. As one can imagine, the Monsanto provisions described here transcend all countries participating in the WEMA project. There is no doubt that these agreements will shape the character and content of IP policies of these research organisations. Indeed, scientists and breeders working with these institutes indicate that the requirements for IP protection have become a more reoccurring phenomenon in research partnerships and hence the need for these organisations to develop their own IP policies. It is not clear yet, how these IP provisions will either facilitate or constrain access to new seed varieties by resource-poor farmers or contradict the public research mandate of many of these organisations. Most interviewees have no clear views on this.

The variety of approaches and emphasis on IP in research partnership agreements, especially those with the CGIAR centers, reflect the lack of consensus among the centers and the varying perceptions among the scientists working in these centers. During the course of this study, some managers and scientists within the CGIAR centers alluded to this absence of a common approach to IP and the fact that the CGIAR policy discussions are a work in progress. It was observed for example that centers such as CYMMIT, CIP and ILRI attach more importance to IP than others.[198] These officials note that there are no known cases where the CG centers have taken out IP for purposes of generating revenue. Rather, the objective is to control and direct the course of commercialization in order to get innovations out through market channels (commercial seed producers). They also note that if the CG centers were sure of funding, they would stick to their mandate of producing global public goods. However, the discussions on IP have been largely motivated by the unpredictable funding environment.[199]

The above analysis points to a number of issues that may inform and shape the development of institutional IP policies among African agricultural research institutions and the implications of such IP policies for access to new agricultural technologies by resource-poor farmers. Firstly, there is no consistency in the nature and scope of the provisions for IP requirements by the various research partner organizations. The variations in such provisions including some that have stringent restrictions on the application of IP arising from research

[198] Interview with an official of CIP on August 3, 2010 at CIP offices in Nairobi, Kenya.

[199] The officials interviewed for this study confirmed that CIP partnership agreements with national programs often contain provisions on IP requiring the use of the product for breeding programs.

supported under such partnerships may result into restrictions on access to new agricultural technologies including new varieties of seeds. Secondly, the varied nature of these IP policies and the provisions in actual contracts could add on the unpredictability about the impact of IP on the public mandate of national agricultural research institutions. Such unpredictability may have the impact of undermining the targeting of agricultural research to crops that are important for smallholder agriculture.

### 4.4.2 Emergence of IPR Brokerage Institutions

Over the last decade, there has been an emergence of institutions that provide 'brokerage' services linking holders of proprietary technologies with researchers and research institutions in developing countries such as those in Sub-Saharan Africa. At the international level the most prominent of these are: the Centre for the Application of Molecular Biology to International Agriculture (CAMBIA); the Public Intellectual Property Resource for Agriculture (PIPRA); and the African Agriculture Technology Foundation (AATF). CAMBIA is an Australian-based initiative whose stated aim is to provide technical solutions that empower local innovators to develop new agricultural innovations.[200] PIPRA, an initiative based at the University of California at Davis, focuses on pooling publicly owned and patented technologies for use by research institutions in developing countries. PIPRA supports innovation in a wide range of sectors including agriculture, and through its network of public interest lawyers, it provides Intellectual Property Rights and commercialization strategy services to increase the impact of innovation, particularly for developing countries and speciality markets.[201]

The African Agriculture Technology Foundation (AATF)[202] is an African-based initiative that seeks to broker access to proprietary technologies that can address the technology needs of smallholder farmers across Africa. The specific focus of AATF is to negotiate access to proprietary technologies and facilitate the delivery of such technologies to resource-poor farmers. The general rule of AATF IP policy is that any product of R&D supported by the foundation should be royalty-free to resource-poor farmers.[203] AATF is not a technology development entity but rather, it plays the role of a broker in a commercial transaction by facilitating negotiations for access to proprietary technologies and acting as some form of insurance against misapplication of such technologies. AATF-brokered partnerships often involve multiple players including multinational seed companies, international agricultural research centres and universities, national agricultural research institutes, funding agencies and seed companies in the technology recipient countries.[204]

The emergence of AATF as an IP brokerage institution and its growing partnership with national agriculture research programs will have profound impacts on access to new varieties of seeds by resource-poor farmers. On the one hand, facilitated access to proprietary technologies could enhance the productivity of smallholder agricultural systems and hence unlock some of the productivity constraints faced by resource-poor farmers in Africa. On the other hand, the restrictions on the use of IP such as the commercialization of products in

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200 See <http://www.cambia.org/daisy/cambia/home.html> (accessed on 1 July 2011).

201 See <http://www.pipra.org/> (accessed on 1 July 2011).

202 See <http://www.aatf-africa.org/> (accessed on 1 July 2011).

203 Interview with an AATF official on August 2, 2010 at AATF offices in Nairobi.

204 See Boadi & Bokanga.

major markets could still undermine the ability of resource-poor farmers to achieve food security through market mechanisms.

### 4.4.3 Multilateral Agriculture Financing Programs

Besides bilateral financing programs discussed in Chapter 3.3, there are other agriculture funding programs whose policies on IP could have an enduring influence on the direction of institutional IP policies.

One such program is the Alliance for a Green Revolution for Africa (AGRA).[205] This multi-million dollar program "works to achieve a food secure and prosperous Africa through the promotion of rapid, sustainable agricultural growth based on smallholder farmers"[206] including through improved access to quality seeds and other productivity-enhancing technologies. According to one senior official, AGRA was originally premised on the Rockefeller Foundation model which does not address issues of IP with regard to funding for agricultural research.[207] Until the time of this study, issues of IP had not arisen within AGRA partly because its founding philosophy is that products of agricultural research should be readily and easily accessible to farmers, especially resource-poor farmers. The Gates Foundation, one of the major funders of AGRA, seems to have the same overall objective, but in contrast with Rockefeller they do have an extensive IP policy and practice and they really do not want to leave IP issue unspecified and unregulated.[208]

One of the unique approaches of AGRA is its declared focus to deliver new crop varieties through conventional breeding and participatory methods. According to its policy statement on plant breeding and genetic engineering,[209] AGRA commits itself to: develop new crop varieties that will withstand pests and diseases; cope with drought, marginal soils and environmental stresses; and dramatically increase farmers' yields using conventional breeding methods. While not ruling out supporting the development and deployment of genetically modified seeds, AGRA considers the deployment of such technologies as first and foremost the right and responsibility of African countries. As of February 2011, AGRA has provided 147 grants to support agriculture across a number of African countries. Of these, at least 64 grants are for development of improved seed varieties. At least 31 grants are for the development of seed varieties of the case study crops discussed in Chapter 2 of this report.[210]

The openness with which programs like AGRA approach issues of IP and biotechnology provides a tremendous opportunity to shape any future IP on new agricultural technologies to remain focused on ensuring access to such technologies by resource-poor farmers and the attainment of MDG 1c objectives. However, this may only be achievable if the agricultural research institutions that are the recipient of AGRA grants set the IP policy agenda by

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205 See <http://www.agra-alliance.org/content/news/detail/1211> (accessed on 1 July 2011).

206 *Ibid.*

207 Interview with a senior official of AGRA on August 2, 2010 at AGRA Offices in Nairobi, Kenya.

208 This position reflect the general position of the Bill & Melinda Gates Foundation which is restated in the notes of a teleconference on intellectual property issues regarding the establishment of a CGIAR Fund available at <http://www.cgiar.org/pdf/cm_Teleconf_Intellectual%20Property%20issues_May%205__Summary%20of%20Discussions.pdf> (accessed on 1 July 2011).

209 See <http://www.agra-alliance.org/section/about/genetic_engineering> (accessed on 1 July 2011).

210 See <http://www.agra-alliance.org/section/about/grants>(accessed on 1 July 2011).

clarifying and articulating their own IP policies rather than waiting for a top-down process driven by partners such as AGRA and others.

## 4.5 Conclusions

This Chapter has examined the factors influencing the development and content of IP policies of African agricultural research institutions. A number of conclusions can be drawn from this analysis. First, it is clear that IP knowledge among researchers and IP managers is low although it is evident that it is gradually increasing.

Secondly, the mandate over national IP policy is spread across agencies covering IP administration, trade and science and technology, often without robust coordination mechanisms. As a result, agricultural research managers and scientists do not have clearly defined policy platforms through which they can influence IP policy development to ensure that such policies are aligned to the needs of resource-poor farmers and the attainment of MDG 1c.

Thirdly, most of the institutional policies that are currently in place are more inward-looking as they focus on the potential for the institutions and the scientists to benefit from IP-protected innovations. There are examples (Ivory Coast) where the policy is directly based on national research interests, but most of the policy instruments do not explicitly articulate the need to use IP to direct agricultural research to address the technology needs of resource-poor farmers.

Finally, the inclusion of IP provisions in research funding agreements is informing and shaping some of the institutional debates on IP. Indeed, it is important that IP managers and researchers within these institutions be more proactive and ensure that the policies adopted conform to their mandate to produce public goods and benefit resource-poor farmers.

# CHAPTER 5 IP POLICIES IN THE NETHERLANDS: WHAT ROOM FOR PRO-POOR INNOVATION?

*Bram De Jonge & Niels Louwaars*

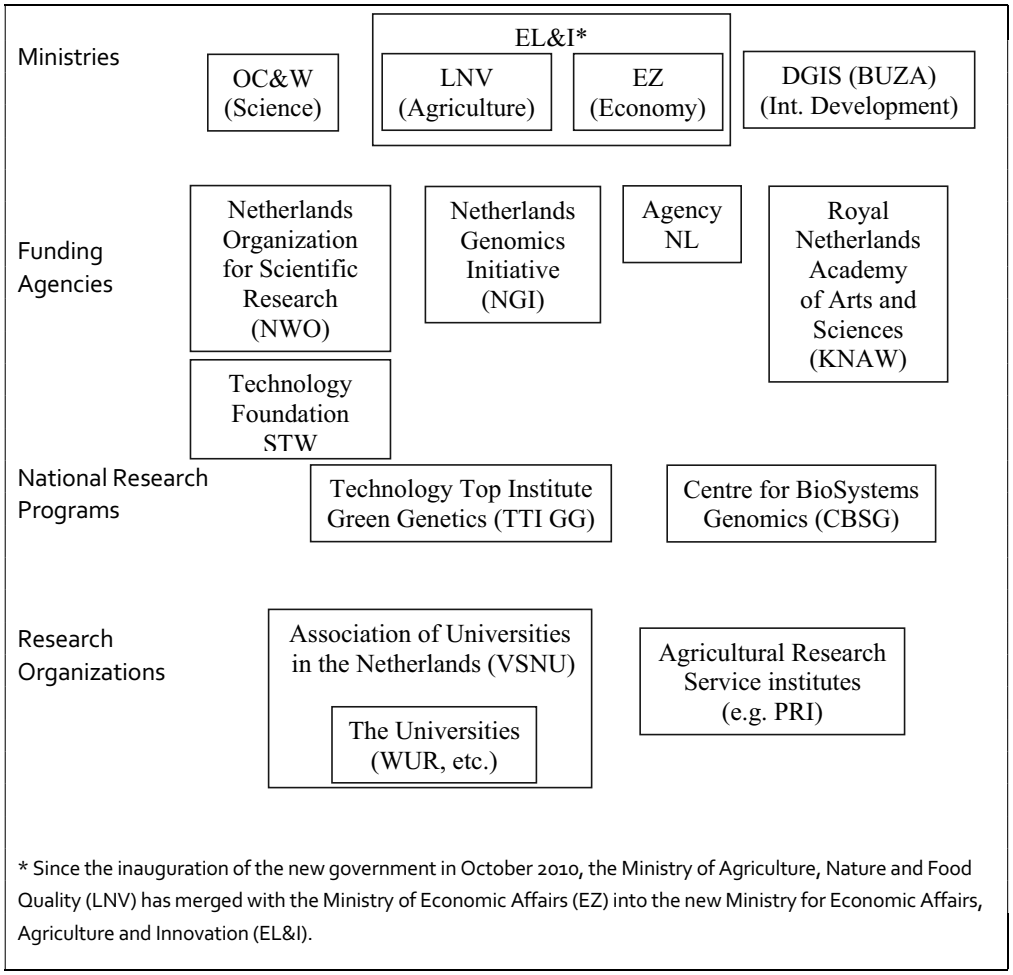
**Abstract**
This chapter focuses on the Netherlands and studies the IP laws, institutional IP policies, and wider organization of the public agricultural research system in order to get a good picture of the main incentives and obstacles for pro-poor innovation – i.e., the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries. We found that valorisation, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is currently the primary driver for IP policymaking in the public agricultural research system. International development considerations do not feature in this discourse and are consequently lacking in almost all IP policies of the actors involved. The relevant ministries do not have a coherent IP policy with respect to the research they finance, and opinions diverge on the need of such a policy. The public funding agencies emphasize the need of IP protection as a necessary means to trigger private investments and technology transfer from the public to the private sector. Public research organizations, in turn, consider their IP portfolio very important for generating alternative income streams through research contracts and collaborations with the private sector. Overall, it became apparent that research and innovation policies, and international development policies, are currently organized and perceived as two worlds apart. As a consequence, most researchers indicated to have little incentives and resources for pro-poor research and technology transfer. Yet, there are some recent voices calling for a reassessment of this situation and for new arrangements in the field of IP protection that suit a more internationally-oriented research and innovation policy.

## 5.1 Introduction

In the next two chapters we discuss the IP policies, practices, and perceptions of the main actors in the Dutch agricultural research system in the context of our central research question: What is the role of IPRs in the management and sharing of knowledge for development (the achievement of MDG 1c). We will investigate how the IP policies and practices in the Dutch agricultural research sector affect *pro-poor innovation* – i.e., the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries. In this chapter, we will focus on the *policy level* and analyse Dutch IP law and the IP policies of those organizations that are responsible for public research in the agricultural sector. Figure 5.1 gives an overview of the main ministries, research funding agencies, and public research organizations that will be discussed. Apart from analysing their institutional IP policies, we will also examine how the research system is financially organized in order to get a good picture of the main incentives and obstacles for research initiatives that are specifically aimed at resource-poor farmers in developing countries.

The next chapter will then focus on the *IP practices* at the level of researchers and IP managers from both the public and private sector.[211]

***Figure 5.1: Overview of the main actors involved in the public agricultural research sector in the Netherlands.***




* Since the inauguration of the new government in October 2010, the Ministry of Agriculture, Nature and Food Quality (LNV) has merged with the Ministry of Economic Affairs (EZ) into the new Ministry for Economic Affairs, Agriculture and Innovation (EL&I).

## 5.2 Dutch IP law

### 5.2.1 IP Rights and Exemptions

In the Netherlands, there are two major IPR instruments available that can be applied for the protection of technologies and new products in the field of plant breeding and plant

[211] Input for these analyses is derived from literature studies and semi-structured interviews with those responsible for IP and agricultural research at ministries (no. of people interviewed: **7**); funding agencies (**5**); national research programs (**2**); researchers (**12**) and IP officers (**7**) at public research organizations; the private sector (**7**); and science interest/advisory organizations (**4**).

biotechnology. These are the National Patent Act (Rijksoctrooiwet 1995),[212] and the Seeds and Plant Material Act (Zaaizaad-en plantgoedwet 2005).[213] Both acts are in line with regional and international regulations to which the Netherlands has assigned, of which the EU biotechnology directive 98/44/EC,[214] the WTO TRIPS Agreement,[215] the EU Community Plant Variety Rights Act,[216] and UPOV 91[217] are most important. The Dutch IP legislation provides that plant innovations can be eligible for both plant variety protection and patent protection.[218] For plant variety protection, a new variety must be new, distinct, uniform and stable.[219] Patent protection is available for *processes* that are not essentially biological, and *materials* that incorporate an invention that fulfils the criteria of novelty, inventive step and industrial applicability, and which is not confined to a particular plant variety – i.e., one cannot patent plant varieties *per se*.[220]

With this legislation in place, the Netherlands finds itself at the international forefront of IP protection and *exemptions* to established property rights are relatively weak. The *research exemption* in patent law only allows for scientific research *on* the invention – i.e., to investigate whether and how it works, and not *with* the invention – to develop a new invention or product.[221] The Seeds and Plant Material Act includes four exemptions. First, the above research exemption applies. Second, the holder of Plant Breeder's Rights cannot exert rights on strictly private and non-commercial use of the protected variety,i.e., farmers can freely handle seed for crops that they consume themselves. Third, the '*farmers' privilege*' holds that farmers are authorized to reuse seeds for a particular group of crops (i.e., most field and pasture crops, no horticultural crops) on their own holding,[222] but not to exchange seeds with other farmers.[223] This exemption also applies to seeds that fall within the scope of the patent law.[224] Farmers other than smallholder farmers (i.e., farmers that produce less than an equivalent of 92 tons of grain on their own holding) are obliged to pay a royalty on such farm-saved seed to the breeder. And fourth, the *breeder's exemption* holds that a protected variety can be used as basic material for the development of a new variety. Yet, due to the provisions of the National Patent Act, this does not apply if the protected variety contains any material that is patented, or if the new product is acquired by use of a process that has been patented.

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212 Available at <http://wetten.overheid.nl/BWBR0007118/geldigheidsdatum_29-09-2009> (accessed on March 16, 2011).

213 Available at <http://wetten.overheid.nl/BWBR0018040/geldigheidsdatum_11-03-2009> (accessed on March 16, 2011).

214 Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31998L0044:EN:HTML> (accessed on March 16, 2011).

215 Available at <http://www.wto.org/english/tratop_e/trips_e/t_agmo_e.htm> (accessed on March 16, 2011).

216 Available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31994R2100:EN:HTML> (accessed on March 16, 2011).

217 Available at <http://www.upov.int/en/publications/conventions/1991/act1991.htm> (accessed on March 16, 2011).

218 Trademarks, geographical indications, trade secrets and copyrights are other forms of intellectual property protection that can be applied.

219 Seeds and Plant Material Act 2005, Article 35.

220 National Patent Act 1995, Articles 2 – 2a.

221 *Idem*, Article 53.3.

222 Community Plant Variety Rights Act 1994, Article 14.2.

223 Seeds and Plant Material Act 2005, Article 57.3.

224 National Patent Act 1995, Article 53c.1.

This is because patent law, which does not include a breeders' exemption, applies in such cases as well.

In line with international and EU legislation, the Dutch IP laws include conditions on *compulsory licenses*. Article 57 of the National Patent Act and Article 61 of the Seeds and Plant Material Act provide together for five different types of compulsory licenses. The minister of economic affairs can grant a license under a patent in cases considered to be in the *public interest*. This term is, deliberately, not further defined in order to give the Dutch government the room to interpret it in accordance to changing circumstances. The Dutch court can oblige a patentee to grant a license in cases of *non-use* (i.e., the use of a patent only to withhold anyone from using the patented technology), and *independence* (i.e., when a patented technology cannot be exploited without use of another patent that has been filed before or at the same time). The last two types of compulsory licenses aim to enable the coexistence of patents and plant breeder rights, holding that a right holder (of either a patent or plant breeders right) may request a compulsory license for non-exclusive exploitation of his invention, which cannot be used without infringing a patent or plant breeders right of earlier date. Yet, for all situations compulsory licensing is considered a final remedy, which means that several conditions for its application apply, e.g., granting will only take place if the right holder is not willing to conclude an agreement on reasonable commercial terms, and only insofar the invention or plant variety for which the license is requested represents "a considerable technical advance of considerable economic significance".[225]

Such conditions make effective use of this instrument very difficult, especially because it cannot be proven *a priori* that, for example, a patented trait constitutes 'significant technical progress of considerable economic interest' when it can be used in a new variety.[226] Furthermore, "it is difficult to demonstrate that one has in vain addressed the patent holder to obtain a license."[227] Together with the fact that several key conditions are not further defined, e.g., what would be in the 'public interest' or 'reasonable economic terms', this may explain why compulsory licenses are very rare. In the Netherlands, the court in The Hague has not reported any applications for compulsory licenses in a period of 10 years after the establishment of the National Patent Act in 1995.[228] With respect to compulsory licenses in the public interest only two applications were filed in the period 1977-2005, and neither one was approved.[229] Even though the use and effectiveness of this instrument was evaluated in 2005 after questions from parliament, the Ministry of Economic Affairs did not see any reason to adapt the current legislation or to further define its terms.[230]

Article 12 of the National Patent Act is relevant for public research organizations, with sub-article 3 stating that a patented invention made by an employee falls under the legal property of the university.[231] The same accounts for students who make an invention in the course of their education.[232] Both students and employees have, however, the right to receive

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225 National Patent Act 1995, Articles 57.4 and 57.5; Seeds and Plant Material Act, Article 61.3

226 Louwaars *et al.* 2009, p. 50.

227 *Idem*, p. 50.

228 Beleidsnota Biotechnologie 2005. Available at <https://zoek.officielebekendmakingen.nl/kst-27428-65.html> (accessed on March 16, 2011).

229 *Idem*.

230 *Idem*.

231 National Patent Act 1995.

232 *Idem*, Article 12.2; Article 12.5 holds that parties can deviate from sub-articles 2 and 3 by written agreement.

a fair compensation,[233] and most universities have established a formula for dividing the net revenues that result from the sale or licensing of a patent to third parties.

### 5.2.2 International Development Considerations

The Dutch government adheres to several international agreements that emphasize the need and responsibilities of developed nations to actively participate in the transfer of technologies and the sharing of knowledge to increase welfare standards in the developing world. Next to the MDGs,[234] the Netherlands is party to the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), which both contain articles on technology transfer and knowledge sharing with developing countries.[235] Also, the WTO TRIPS Agreement states that

"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[236]

These objectives are, however, not reflected in the Dutch IP law. Even though the law is considered to be compatible with TRIPS, no reference is made to the above article, and later amendments in the context of the WTO Doha Declaration[237] are left to the European level.[238] Furthermore, the provisions on compulsory licenses, which could, in theory, be used for international development objectives, appear to be impractical to apply.

The only context in which development considerations are, to some extent, entering discussions on Dutch IP law is the current debate on patents and Plant Breeder's Rights. In 2009, the ministries of Agriculture, Nature and Food Quality and of Economic Affairs[239] asked the Centre for Genetic Resources, the Netherlands, to do a study on the future of public and private plant breeding in light of developments in patent law and Plant Breeder's Rights. The resulting report was presented to the Dutch Parliament on April 19, 2010, together with the official standpoint and response to the report's policy recommendations of the two ministries (see Box II-8).[240] Amongst others, the report indicates that the "free availability of genetic diversity for breeding decreases when genetic materials are patented", while Plant Breeder's Rights are reported to make "a positive contribution to innovation and hardly [cause]

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233 *Idem*, Article 12.6.

234 Technology cooperation is widely considered to be of crucial importance for reaching the Millennium Development Goals. See <http://www.unmillenniumproject.org/documents/Science-complete.pdf>(accessed on March 16, 2011).

235 CBD 1992, Articles 17 – 19; ITPGRFA 2001, Articles 7, 8 and 13.

236 TRIPs 1995, Article 66.2.

237 These concern amendments on the TRIPS agreement in relation to global health. See <http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> (accessed on March 16, 2011).

238 See <http://ec.europa.eu/internal_market/indprop/docs/medicines/implementation_en.pdf> *(*accessed on March 16, 2011).

239 Since the inauguration of the new government in October 2010, the Ministry of Agriculture, Nature and Food Quality has been merged with the Ministry of Economic Affairs into the new Ministry for Economic Affairs, Agriculture and Innovation (EL&I).

240 Available at <www.minlnv.nl/txmpub/files/?p_file_id=2000541> (accessed on March 16, 2011).

restrictions."[241] The importance of the free availability of genetic diversity for food security is emphasized in both the report and the letter of the ministries. For this and other reasons, the two ministers propose to introduce a *restricted* breeder's exemption[242] in the Dutch patent law and to table the issue in the EU and beyond (e.g., TRIPS) in order to discuss more far-reaching solutions.[243]

**Box II-8: *Breeding Business***

*The report Breeding Business: The future of plant breeding in the light of developments in patent rights and plant breeder's rights[244] describes the trends in technology development, IP protection and consolidation in the sector. The report concludes that if a number of policy objectives are to be attained, changes in the patent system are required at three levels: i) reducing the levels of strategic patenting by the applicants; ii) a radical improvement of patent quality based on stricter examination guidelines at the patent offices; and iii) the introduction of a full breeder's exemption in national and EU patent laws. A full breeder's exemption is an exemption of the use in plant breeding of genetic material falling under the scope of a patent, and also of the commercialization of the new varieties that result from this, even if they carry a patented trait.*

*The two ministries, in their letter to Parliament, subscribe to the conclusion that the patent system creates problems in the sector. They propose to introduce a restricted breeder's exemption in the Dutch patent law, also because a full breeder's exemption would first require an amendment of the EU Biotechnology Directive. For that purpose, the ministries further announce to table the issue in the EU and beyond. At the same time, they emphasize the need for the sector to discuss and develop solutions that are to reduce strategic patenting. For more information on this debate, see Chapter 6.*

### 5.2.3 Conclusion

There is no reference to development objectives in Dutch IP laws, for example with regard to promoting technology transfer in line with TRIPS Art. 66.2. The legislation provides for strong intellectual property protection, to which the various exemptions are relatively weak. The research exemption, for example, only allows for scientific research *on* the invention and not *with* the invention. The breeder's exemption, which allows breeders to use protected varieties to develop new varieties, does not apply if the protected variety contains any material that is patented, since patent law does not include such exemption. This may change, however, as the Dutch government has recently announced to introduce a restricted breeder's exemption in the Dutch patent law, and to start discussing more extensive solutions at the international level. A full breeder's exemption, and a more liberal research exemption, will positively affect the availability of genetic material for further research and breeding, which is essential for reaching global food security. Compulsory licenses are another tool to secure the availability

241 Louwaars *et al.* 2009, p. 56.

242 *I.e.*, an exemption of the use of genetic material falling under the scope of a patent for plant breeding, but not of the commercialization of the varieties originating from this activity when these varieties carry a patented trait, as already implemented in Germany, France and Switzerland.

243 Available at <www.minlnv.nl/txmpub/files/?p_file_id=2000541> (accessed on March 16, 2011).

244 Louwaars *et al.* 2009.

of IP-protected technologies but their applications are very rare due to the impractical conditions attached.

## 5. 3 Ministries

### 5.3.1 The Ministry of Agriculture, Nature and Food Quality[245]

In the Netherlands, there are several ministries that influence policymaking with respect to agricultural research and development. One of the main actors is the ministry of Agriculture, Nature and Food Quality (LNV).[246] On its website, the ministry states that it seeks to "strengthen the international competitive position of the agriculture sector based on socially responsible enterprise."[247] For this purpose, it aims to create the necessary frameworks and directives, mostly in close collaboration with the sector itself, and provides funding for research and development in the field. The ministry is mainly responsible for basic funding (financing the so-called first flow, see Box II-9) of Wageningen University, the Dutch agricultural and life sciences university, and the various agricultural schools. It also provides through research programs for some 50% of the funds of the Agricultural Research Service (DLO institutes), which are not-for-profit private research institutes that together with the university form Wageningen University and Research centre (Wageningen UR).[248]

**Box II-9:** ***Public Research Funding in the Netherlands***

*Public research is financed by three different flows of funds: 1) The first flow of funds consists of direct government funding on the basis of lump-sum financing; 2) The second flow of funds comes from the Netherlands Organization for Scientific Research (NWO) and is distributed on a competitive basis to the best researchers and research groups; 3) The third flow of funds is funding in return for contract research carried out for third parties, including public authorities, companies, charity funds, and foreign subsidies. Specialized research programs such as Technology Top Institute Green Genetics (TTI GG) are also part hereof.*249 *Another source of income for universities is the student tuition fees. Figure 5.2 below shows the relative importance of these income streams for all Dutch universities in 2007.*[250]

245 Since the inauguration of the new government in October 2010, the Ministry of Agriculture, Nature and Food Quality has been merged with the Ministry of Economic Affairs into the new Ministry for Economic Affairs, Agriculture and Innovation (EL&I).

246 As an abbreviation we will refer to the 'ministry of agriculture' in the text below.

247 See <http://www.minlnv.nl/portal/page?_pageid=116,1640375&_dad=portal&_schema=PORTAL> (accessed on March 16, 2011).

248 See <http://www.wageningenuniversity.nl/UK/about/history/> (accessed on March 16, 2011).

249 Ministry of Education, Culture and Science 2008. Available at <http://english.minocw.nl/documenten/ Institutioneel-overzicht-ENGversie-met%20grote%20letter_140808_.pdf>(accessed on March 16, 2011).

250 Vrienden van wetenschap 2009. Avaliable at <http://www.vriendenvanwetenschap.nl/ sites/default/ files/wetenschap%20in%20vogelvlucht.pdf>(accessed on March 16, 2011).

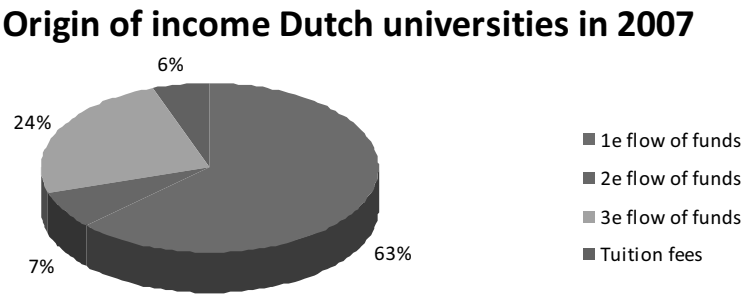


*Fig. 5.2. Origin of income Dutch universities in 2007.*

With respect to IP, the ministry is responsible for the Seeds and Plant Material Act and represents the Netherlands at UPOV, at which meetings it plays an active role. The ministry is increasingly monitoring the working of different IPR instruments in the sector (see Box II-8), but concerning agricultural research that the ministry finances it does not employ an IP policy. Only in its subsidy regulations for research executed by the Agricultural Research Service,[251] the ministry has included Article 13, which holds that the revenues of the exploitation of knowledge and IPRs acquired from research funded by the ministry should be used for maintaining the knowledge infrastructure on the priority expertise fields established by the minister. This is to make sure that publicly funded research supports the public knowledge infrastructure even when the results may not be freely available anymore because of exclusive licenses or IP protection. Yet, it was admitted that the implementation of this article is difficult to enforce and to monitor.

### 5.3.2 The Ministry of Education, Culture and Science

Two other ministries that impact agricultural research and development through research funding are the ministry of Education, Culture and Science (OCW),[252] and the ministry of Economic Affairs (EZ). The former coordinates science policy for the entire national government. Hereby, its mission is "to create a research climate that fosters world-class scientific achievements and promotes the welfare and well-being of society at large."[253] Approximately two-thirds of research funding in the Netherlands comes from the ministry of education, either through direct funding to universities or via the (co-)financing of research funding agencies (see Box II-9); in the field of agriculture this is much less because of the involvement of the Ministry of Agriculture. Yet, the ministry of education does not have an IP policy and is not planning to develop one. The main reason for this is that the ministry values the autonomy of the sector and does not want to interfere much with the work and policies of the institutions it finances, i.e., both the research organizations and the funding agencies. The

[251] Regeling Subsidie Stichting Dienst Landbouwkundig Onderzoek 2009. Available at <http://www.st-ab.nl/wettennr02/0165-007_Regeling_subsidie_Stichting_Dienst_Landbouwkundig_Onderzoek.htm> (accessed on March 16, 2011).

[252] As an abbreviation we will refer to the 'ministry of education' in the text below.

[253] See <http://english.minocw.nl/english/science/index.html> (accessed on March 16, 2011).

ministry, which does not have an IP officer, considers the individual institutions to be best positioned to deal with IP issues and leaves all responsibilities to the sector itself.

The only area that links to IP in which the ministry has some interest is that of *valorisation* (see Box III-10). Valorisation is defined as "the process of value creation out of knowledge, by making knowledge suitable and/or available for economic and/or social use and to translate that knowledge into competitive products, services, processes and new economic activities."[254] In 2005, the ministry sent a letter to the board of all universities to remind them of the third task of universities as portrayed in Article 1.3 of the Law on Higher Education and Scientific Research (WHW)[255] – i.e., the transfer of knowledge for the benefit of society next to objectives of research and education. Despite the fact that policymakers are quick to mention the need of both economic and social valorisation, the former has received most attention so far. Hereby, the number of patents, spin-offs, revenues, and the like, are often used as criteria for measuring success.

**Box II-10: *Valorisation***

*The concept of valorisation is central to debates on research, innovation and entrepreneurship in the Netherlands, and must be positioned against the background of the so-called knowledge paradox: The perception that even though the Netherlands is a leader in scientific research, most of the knowledge generated does not get translated into innovative and commercial products or processes. In order to counter this situation, the Dutch government has started several initiatives, amongst which are an Interdepartmental Program Directorate on Knowledge and Innovation consisting of 10 different ministries, and the Dutch Innovation Platform.*

*The Innovation Platform is a national body designed to unite companies, knowledge institutions and government in order to "strengthen the Netherlands' capacity for innovation so that our country can once more become a trailblazer in the international knowledge economy" and to ensure "that the Netherlands becomes one of the world's top five knowledge economies."[256] They initiated the signing of a national valorisation agenda (08-12-2008) in which representatives of government, employers' federations, funding organizations, science associations and research institutions describe the actions to which they commit in order to stimulate the translation of knowledge and research into actual value for society.[257]*

*Key commitments of the government are to provide for several valorisation subsidies, programs, and instruments and to raise awareness and stimulate entrepreneurship through policies of the national research funding organizations.[258] In this context, the Ministry of Economic Affairs recently published an adapted subsidy regulation that incorporates a valorisation program.[259] Within this program, Dutch universities can, in cooperation with at least one Netherlands-based company, apply for grants to finance their valorisation activities and IP protection costs.*

254 Translated from <http://www.ez.nl/Home/Programma_Valorisatie> (accessed on March 16, 2011).

255 Available at <http://www.st-ab.nl/wetten/0718_Wet_op_het_hoger_onderwijs_en_wetenschappelijk_onderzoek_WHW.htm> (accessed on March 16, 2011).

256 See <http://www.innovatieplatform.nl/en/platform/mission/> (accessed on March 16, 2011).

257 Innovativon Platform 2008. Available at <http://www.rijksoverheid.nl/documenten-en-publicaties/rapporten/2008/12/03/valorisatieagenda-kennis-moet-circuleren.html> (accessed on March 16, 2011).

258 See the e-portal <www.technopartner.nl> (accessed on March 16, 2011).

259 Available at <http://www.technopartner.nl/resources/uploads/files/gepubliceerde%20regeling%20stcrt-2010-7633.pdf> (accessed on March 16, 2011).

### 5.3.3 The Ministry of Economic Affairs[260]

The Ministry of Economic Affairs (EZ) is responsible for the National Patent Act and represents the Netherlands at meetings of the WTO and WIPO. The ministry makes fixed contributions to a number of research (funding) organizations and finances the Netherlands Patent Office. In its regulations on research funding, the ministry demands the *responsible use* of the results that derive from the research in accordance with the subsidy application.[261] This means that the utilization of IPRs is the responsibility of the subsidy recipient, yet, that utilization must suit the objectives of the research project for which the funding was provided, and otherwise the ministry can modify or withdraw its funding. The subsidy recipient needs to report to the ministry on research progress and (intended) use of IPRs. The ministry intends to fund public research that has the potential to lead to new market opportunities for businesses as it aims "to achieve a prosperous, sustainable and enterprising Netherlands as part of an open global economy."[262]

This is also reflected in the ministry's valorisation program and the study *Taking advantage of patents. Effective cooperation between companies and universities*,[263] which was commissioned by the ministry[264] in order to advise universities on the use of IPRs and to stimulate knowledge and technology transfer with private partners. The new subsidy regulation on valorisation (see Box II-10) aims specifically to "strengthen the valorisation process in the Netherlands",[265] and demands that the IPRs resulting from the financed activities should be transferred to the private sector partners within 30 months.[266] Like the Ministry of Agriculture, the Ministry of Economic Affairs demands that the revenues obtained from transferring IPRs should be reinvested in "the primary activities" of the public research organizations.[267]

### 5.3.4 The Directorate-General of International Cooperation of the Ministry of Foreign Affairs

The Directorate-General of International Cooperation (DGIS) of the Ministry of Foreign Affairs[268] is responsible for the coordination, implementation and financing of the Dutch

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260 Since the inauguration of the new government in October 2010, the Ministry of Agriculture, Nature and Food Quality has been merged with the Ministry of Economic Affairs into the new Ministry for Economic Affairs, Agriculture and Innovation (EL&I).

261 Kaderbesluit EZ-subsidies 2008, Article 40. Available at <http://www.senternovem.nl/mmfiles/EZ6%20kaderbesluit%20subsidies%20Staatsblad%20499%20met%20bijlagen_tcm24-289228.pdf> (accessed on March 16, 2011).

262 See <http://english.ez.nl/english/Organisation/The_Ministry.htm> (accessed on March 16, 2011).

263 Hanneman, H.W., 2007. Available at <http://vno-ncw.nl/SiteCollectionDocuments/ Cmsdocs/taking_advantage_of_patents.pdf> (accessed on March 16, 2011).

264 Together with the VSNU and VNO-NCW.

265 Regeling tot wijziging van de Subsidieregeling starten, groeien en overdragen van ondernemingen ter invoering van het Valorisatieprogramma 2010, Article 5.1. Available at <http://www.technopartner.nl/resources/uploads/files/gepubliceerde%20regeling%20stcrt-2010-7633.pdf> (accessed on March 16, 2011).

266 *Idem*, Article 5.2.2.c.

267 *Idem*, Article 5.2.2.c.

268 As an abbreviation we will refer to 'DGIS' in the text below.

development cooperation policy.[269] Up till some years ago, the department had its own research program and research subsidies were subject to some conditions on the use of IPRs. The main condition was that the department *co-owned* any IP that came out of the research and, consequently, could *co-decide* on its use. According to one interviewee, this was to make sure that government would not pay two or three times for the same research, i.e., first for the research itself, second for accessing the research products once these are protected by IPRs, and third for ordering the production of the product elsewhere (e.g., for humanitarian purposes). As a co-owner, DGIS could set conditions on how IPRs were managed and transferred, for example by demanding the inclusion of *humanitarian use clauses* if the rights were licensed out to a third party (see Box II-11: *Humanitarian Use Licensing*).

Currently, the department is the principal funder of the Science for Global Development program (WOTRO) of the Netherlands Organization for Scientific Research (NWO). It also finances several research projects under the *Schokland Agreements* of 2007,[270] amongst which is this project, in order to stimulate the fulfilment of the Millennium Development Goals.[271] Hereby, the department does not employ its aforementioned IP policy anymore, mainly because most research does not involve technological innovations and, thus, patentable matter. Yet, the former minister continued to urge "Dutch universities and research institutes to adopt institutional IP policies that take account not only of valorisation of knowledge and incentives for researchers, but also the importance of access to knowledge and freedom to operate for development purposes."[272]

**Box II-11: *Humanitarian Use Licensing***

*Humanitarian use licensing, also called equitable access licensing, is a generic term for all kinds of contract clauses and licensing forms that secure the possibility for inventors and technology suppliers to share their IP with people in need, or with organizations who work to benefit those in need. Normally, they set the conditions for the provision of access to innovations on a royalty-free basis or at a reduced cost in specific countries or for specific groups or applications, e.g., in the form of field of use or territory licenses. In this way, such licenses can ensure that knowledge and technologies stay available for humanitarian use, while maintaining the incentive function of exclusive IP rights.[273] More information on the use of humanitarian use licenses is provided in Chapter 6.*

### 5.3.5 International Development Considerations

As part of a coherent national policy, DGIS would like to see other ministries design and adopt IP policies that protect the accessibility of the products of research financed with public money for development purposes. Given the perceptions at the other ministries, however, it is not likely that this will happen easily. Apart from the perspective that IP matters fall under

269 See <http://www.minbuza.nl/en/Key_Topics/Development_Cooperation> (accessed on March 16, 2011).

270 Available at <http://www.worldconnectors.nl/pdf/86.pdf> (accessed on March 16, 2011).

271 Another initiative in the field of IP financed by DGIS is the National Partners Initiative of the Central Advisory Service on Intellectual Property of the CGIAR, see <http://www.cas-ip.org/projects/npi/> (accessed on March 16, 2011).

272 Koenders 2008.

273 This information is derived from <http://www.cas-ip.org/ip-agriculture/equitable-access-licences/> (accessed on March 16, 2011).

the responsibility of, and are best handled by, the sector itself, most interviewees do not see a need for DGIS' former IP strategy. The problem of paying more than once for the same research was not mentioned by the other interviewees, and non-IP issues such as lack of technological capacity and financial resources were considered stronger impediments on access to foreign technologies than matters of IP, for which compulsory licensing instruments were generally regarded a sufficient solution. Furthermore, several interviewees were of the opinion that IP protection would not impede access to foreign technologies in developing countries, because these countries have, according to them, no operational IPR law in place or because 'our' IPRs are not filed there. On the contrary, because a fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public, use of patented inventions in developing countries will even be facilitated.

Yet, the argument that researchers in developing countries are, in practice, free to use technologies that are protected by foreign IPRs is questionable for several reasons:

1) Many developing countries already have, or are in the process of, implementing IP legislation in the context of the WTO TRIPS Agreement, of which most developing countries are a signatory/member. Furthermore, many even have agreed to more stringent IPR regulations through the signing of bilateral trade agreements with industrialized countries.[274] These countries risk serious trade sanctions in case of noncompliance with the agreed regulations.
2) Companies or research institutions operating in developing countries where, for example, most biotechnology patents are not filed and Plant Breeder's Rights are non-existent, will still have to comply with the relevant IPRs when exporting their products or technologies to a country where these IPRs are valid in order to avoid infringement suits.
3) The use of new inventions in the field of agriculture often demands access to materials and know-how and not merely the information disclosed in patent applications.[275] In case the IP holder agrees with sharing such information or materials, it is common practice that the recipient will have to sign a contract or material transfer agreement that will oblige him to respect the IP rights involved.

In its recent report *Less Pretention, More Ambition. Development Aid that Makes a Difference* (2010), the Dutch Scientific Council for Government Policy (WRR) warns the government of the negative impact that IPRs can have on developing countries. The report states that the current international agreements on IPRs make it much more difficult for developing countries to 'borrow' foreign technologies, something that the developed countries did at length in the period 1950-1980 and which helped them to get to the point where they are now.[276] As such, the report concludes that non-financial tools, such as "less strict Intellectual Property Rights" can make "a bigger contribution to development than classic aid."[277] In Chapter 6, the positive and negative effects that IPRs can have for developing countries are discussed in more detail.

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274 See Chapter 3, and PART I.

275 See for more information Chapter 6.

276 Wetenschappelijke Raad voor het Regeringsbeleid, 2010, p. 93. Available at <http://www.wrr.nl/english/content.jsp?objectid=5190> (accessed on March 16, 2011).

277 *Idem*, p. 2.

Despite these diverging positions on the effects of IPRs for developing countries, all interviewees consider *agenda setting* the best tool to incorporate a development focus in public research. In 2008-2009, the ministry of education published, in close collaboration with other ministries[278] and the relevant scientific (umbrella) organizations, the internationalization agenda *The Boundless Good*,[279] in which the need for more synergism between public research and development cooperation is acknowledged. Apart from DGIS, the Ministry of Agriculture is getting more active in this perspective by formulating research priorities that also include development-focused research and technology transfer objectives in some of the research programs it finances (see Box II-12). Yet, most interviewees stress that the focus on development issues in public research is also a political issue, which very much depends on how the government chooses to distribute funds.

**Box II-12:** ***Agenda Setting: The case of Technology Top Institute Green Genetics***

*Technology Top Institute Green Genetics (TTI GG) is a public-private partnership between "the majority of the Dutch Green Genetics industry and the major players in the Dutch plant sciences,"[280] which receives half of its total budget from the Dutch ministries of agriculture (LNV) and economic affairs (EZ). TTI GG aims to strengthen the knowledge base of the Dutch plant breeding sector by closer cooperation with research and education institutions, and "to convert knowledge developed in the program into value for the Dutch economy."[281] The initiative did initially receive funding for the period 2007-2010, but because of its success a second round or even structural government funding is currently being discussed. The interviewees at the ministry of agriculture indicate that in case the ministry is going to commit itself financially for a longer period of time, it wants to be involved in setting the research agenda. This would mean that broader, international objectives in the area of, for instance, climate change and global food security, will feature next to research goals that merely aim to strengthen the Dutch plant breeding sector.*

### 5.3.6 Conclusion

From the above we have to conclude that the Dutch ministries do not have a coherent IP policy with respect to the research they finance. The only condition that is included in some of the ministries' subsidy regulations holds that the revenues obtained from transferring IPRs should be reinvested in the knowledge infrastructure. The context in which IPRs are most discussed is that of valorisation, which has become a sort of buzzword in the Netherlands to emphasize the need for turning knowledge into value for (Dutch) society. Together with the narrow focus on the Dutch economy and its competitive position, international development considerations are totally lacking from this discourse. The Directorate-General of International Cooperation (DGIS) is the only department that in the past utilized an IP policy

278 *I.e.* the ministries of agriculture (LNV), economic affairs (EZ), foreign affairs (BZ) and the department of international cooperation (DGIS).

279 Available at <http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2009/10/15/bijlage-a-rapport-internationale-positionering-van-nederlandse-onderwijs-en-kennisinstellingen.html> (accessed on March 16, 2011).

280 TTI GG 2005, p. 1. Available at <http://www.groenegenetica.nl/pro1/general/ start.asp?i=0&j=0&k=0&p=0&itemid=71> (accessed on March 16, 2011).

281 *Idem*, p. 12.

to secure the availability of IP protected technologies for humanitarian use. Yet this policy is no longer operational, and the need for such policy is not recognized at other ministries. Furthermore, the ministry of education (OCW), which is responsible for the bulk of the research funding, strongly opposes a central IP policy under the guise of protecting the autonomy of the public research sector. Agenda setting is broadly considered the best tool to incorporate a development focus in public research, but it is emphasized that the resources available depend on political decision-making.

### 5.4 Research Funding Agencies

Next to the ministries, the research funding agencies are the principal institutions that may impact matters of IP and development cooperation at the research level. In this section, we will briefly discuss five agencies that (co-)finance agricultural research programs in the Netherlands.

#### 5.4.1 The Netherlands Organization for Scientific Research

The Netherlands Organization for Scientific Research (NWO) is responsible for distributing the second flow of funds, i.e., government funding for scientific research that is distributed on a competitive basis to the best researchers and research groups (see Box II-9). The standard regulations apply to all NWO subsidies.[282] Articles 16 holds that, in line with the National Patent Act, "the university's status as employer confers on it the legal ownership of any patent rights relating to research funded by NWO/STW". Yet, it continues with stating that "the university must share these rights equally with NWO or STW/NWO", and (Article 17)[283] that "NWO or STW/NWO shall have the right to claim co-ownership".[284] Nevertheless, the NWO Department of Earth and Life Sciences (ALV) does not actively manage the IPRs that result from the research it finances. Apart from reporting the number of patents and licenses as an important research output to its funder, i.e. the ministry of education, IP issues that come to the fore are passed on to Technology Foundation STW, which has much more experience in this field.

#### 5.4.2 Technology Foundation STW

Technology Foundation STW is the part of NWO that deals with technical sciences, aiming to bring researchers and potential users of the research results together right from the start.[285] It is financed by both the ministries of education and economic affairs. STW co-owns all IP that

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282 NWO 2007. Available at <http://www.nwo.nl/files.nsf/pages/SPES_5VEDDR_Eng/$file/Reg_subsidieverlening_NWO_23_mrt_05_Eng.pdf> (accessed on March 16, 2011).

283 Article 12.5 of the National Patent Act 1995 holds that parties can deviate from these standards by written agreement.

284 Article 18 holds, furthermore, that the "exploitation of joint intellectual property rights is to be managed by NWO or STW/NWO, so far as possible by mutual agreement with the host institution." Yet, in a written response to a question for clarification NWO let us know that it does not aim to become owner of the results of the research it finances.

285 STW 2008. Available at <http://www.stw.nl/NR/rdonlyres/BF04E342-37FA-458F-9E3B-E6CEF02D9A3C/0/FolderSTW_Engels.pdf> (accessed on March 16, 2011).

comes out of its research funding and has a strong focus towards *utilization*, i.e. the application of research results in business and society. It also has a duty to generate revenues from the transfer of these results to parties that want to apply them commercially. The foundation attaches considerable importance to knowledge protection in order to facilitate knowledge transfer, and research proposals need to include a *user committee* consisting of a minimum of four users, at least half of whom are from industry.[286] Members of this committee that contribute substantially (see Box II-13) to the funding of the project are entitled to an option, including a right of first refusal, i.e. the right to purchase or license IP from the project before the offering is made available to others. The net income from the transfer of IP to commercial partners flows back to the public research partner(s) involved, as STW is a non-profit organization. With respect to its IP portfolio, the foundation utilizes various strategies to stimulate their wide dissemination into society, for example by providing exclusive licenses only for specific, non-competing application areas, and by applying anti-freezer clauses or best endeavours obligations.[287] STW also demands that, when selling IPRs to a third party, the public research organizations maintains the right to use the results "for the purpose of non-commercial research and teaching".[288]

**Box II-13:** ***IP Options and the Relative Contributions of the Private Sector***

*There has been debate whether the relative contributions of companies that have a seat in an 'user committee' of a public research project, or even of companies that participate in public-private partnerships, justifies them having a right of first refusal to the IP generated. Some interviewees reported that companies used to get a cheap ride by joining such committees for little money while being in control of any valuable IP that could come out of it. For this reason, Technology Foundation STW has sharpened its policies by demanding a substantial contribution and stating that "STW does not regard a contribution of less than 10% of the total funding allocated to the project (necessary financial resources plus in-kind contributions) as substantial."[289] Still, opinions will differ on whether that is substantial enough to warrant the right of first refusal.*

*With respect to public-private partnerships, the Technology Top Institute Green Genetics (TTI GG) presents an example of how different IP arrangements can be established for parts of the research program that have a different funding ratio, providing either the public or private partners with a right of first refusal.[290] Over the whole budget, the ratio of funding by government, industry, and public research organizations is approximately 50%, 28% and 22% respectively. Hereby, it was decided that the industry partners lead the consortium and have a 50+% vote in all decision-making bodies.*

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286 STW 2009a, Article 3.1. Available at <http://www.stw.nl/NR/rdonlyres/B9FD0D36-8694-4B28-87AA-830C28C02B2D/0/Generalfundingconditions20091215.pdf> (accessed on March 16, 2011).

287 *Idem*; Other aspects of STW's IP policy include royalty-free research and education licenses, and regulations on liability/indemnity, confidentiality and scientific publishing, see also <http://www.stw.nl/ Over+STW/ Kennisexploitatie.htm> (accessed on March 16, 2011).

288 *Idem*, Article 8.3.c.

289 STW 2009b. Available at <http://www.stw.nl/NR/rdonlyres/F1122A43-3EF1-49A2-82FA-7901A0119CFB/0/MainPrinciplesIPPolicy20100713.pdf> (accessed on March 16, 2011).

290 TTI GG 2005; TTI GG 2008, Article 4. Available at <http://www.groenegenetica.nl/pro1/ general/ start.asp?i=0&j=0&k=0&p=0&itemid=72> (accessed on March 16, 2011).

### 5.4.3 Netherlands Genomics Initiative, Agency NL & the Royal Netherlands Academy of Arts and Sciences

Three other funding bodies are the Netherlands Genomics Initiative (NGI), Agency NL, and the Royal Netherlands Academy of Arts and Sciences (KNAW). To start with the first two, NGI is an example of a temporary government funding program that aims to strengthen the Dutch knowledge and research sector in a specific area.[291] Agency NL is a department of the Ministry of Economic Affairs that implements government policy for sustainability, innovation, and international business and cooperation. Hereby, it strives for long-term welfare through economic growth and a competitive, innovation-based economy.[292] Both agencies do not co-own the IP that results from the research they finance and therefore do not have an official IP policy. Yet, both organizations focus strongly on public-private collaborations and emphasize the application of IPRs in that context. NGI, for example, has set for the research programs and consortia it finances quantitative valorisation targets, adding in total to 185 patent applications in 4 years (see figure 5.3). The main reason behind this is to raise awareness at public researchers that valorisation targets are as important as the traditional scientific outputs, e.g., publications. Agency NL, in turn, demands a good business plan in which the IP position and strategy of the research partners are well thought out before funding is provided.

***Figure 5.3: NGI valorisation targets based on € 500 million of research investments[293]***

| Valorisation | NGI Ambition 2008-2012 (Absolute goals) |
|---|---|
| Invention Disclosures | 370 |
| Patent Applications | 185 |
| Licenses | 150 |
| Investments Private Parties | € 45 m |
| Spin-offs | 16 |

The Royal Netherlands Academy of Arts and Sciences (KNAW) is an advisory body to the Dutch government, but also (co-)finances several research institutions and programs.[294] The organization does not have an IP policy in place but recognizes the growing importance of IP related issues and has made a start to build expertise in this area.

### 5.4.4 International Development Considerations

All funding agencies are quick to acknowledge that IPRs are not a goal in itself and that, for example, the number of patent applications does not say much about the quality of research. Yet, IPRs are generally perceived as an important or necessary means to trigger private

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291 NGI received its first funding for a five-year period in 2003, and a second time for the period 2008-2012, see <http://www.genomics.nl/> (accessed on March 16, 2011).

292 See <http://www.senternovem.nl/english/about_us/index.asp> (accessed on March 16, 2011).

293 NGI 2007, p. 16. Available at <http://www.genomics.nl/News%20archive/NGI_2.aspx> (accessed on March 16, 2011).

294 See <http://www.knaw.nl/Pages/DEF/26/105.bGFuZz1FTkc.html> (accessed on March 16, 2011).

investments and technology transfer from the public to the private sector and in some cases such as NGI the number of patents is an explicit target. Reflection on the possible consequences of IP protection on the accessibility of research results for humanitarian purposes, i.e. the use by parties that cannot pay for licenses and royalties (see Box II-11), is generally lacking. Some interviewees referred to the lack of access to essential medicines in developing countries and the use of humanitarian use clauses and compulsory licenses in that respect, but they did not know about similar problems in the field of plant breeding and biotechnology. The funding agencies that co-own IP have no specific policy in this area and do not have experience with the use of humanitarian clauses in the licenses they provide to the private sector. Yet, an interviewee at Technology Foundation STW stressed that the foundation could easily incorporate such humanitarian clauses in its contracts if the research partners, public or private, would ask for that. But the suggestion that the funding agency could take such initiatives by itself as well was not being discussed so far.

More is being done with respect to the accessibility of research *literature*. The Netherlands Organization for Scientific Research (NWO) has recently established an Incentive Fund for Open Access Publications.[295] Through this five million euro fund, every NWO project has a budget for publishing in open access journals or purchasing the rights for open access of a paper. This initiative can strongly improve the accessibility of Dutch scientific knowledge for libraries and research organizations in developing countries.

Apart from this initiative and some specified development programs,[296] considerations with respect to global access and international development are mostly lacking at the level of the Dutch research funding agencies. An important reason for this is the strong focus on economic valorisation and collaborations with the Dutch private sector in the research programming. Consequently, international development issues are by most interviewees considered a 'separate world' that falls outside their day-to-day business, or for which they have no assignment and, thus, resources to deal with. As a possible improvement of this situation, several interviewees argued that more attention should be paid to so-called social valorisation and the development of criteria that can evaluate non-economic results and applications of public research. This would then create a context in which development issues could get a place as well.

### 5.4.5 Conclusion

The main funding agency in the Netherlands, the Netherlands Organization for Scientific Research (NWO), co-owns all IP that results from the research it finances together with the research organization involved. Yet, the Department of Earth and Life Sciences (ALV) does not actively manage IPRs, and leaves most matters of IP protection to Technology Foundation STW. This is a part of NWO that prioritizes the application of research results in society and, for that purpose, has developed an extensive IP policy. Two other funding bodies, Netherlands Genomics Initiative and Agency NL, do not (co-)own IP and have no explicit IP policy in place. Yet, both agencies stimulate IP protection by setting patent application targets or demanding a strong IP strategy before funding is provided. International

[295] NWO 2010. Available at <http://www.nwo.nl/files.nsf/pages/ NWOP_6AXK5Z_Eng/ $file/ Open%20Access_Eng.pdf> (accessed on March 16, 2011).

[296] *E.g.* Science for Global Development program (WOTRO), see <http://www.nwo.nl/nwohome.nsf/ pages/NWOA_6UB9S8_ENG> (accessed on March 16, 2011).

development considerations do not feature in the policies of these funding agencies, and IP tools such as humanitarian use clauses are not used. The NWO Incentive Fund for Open Access Publications is a recent initiative that can improve global access to Dutch scientific knowledge.

## 5.5 Public Research Organizations

To really analyse the effects of the various policies of the ministries and funding agencies on agricultural research and the room for pro-poor innovation and technology transfer, we have to focus now on the situation at the public research organizations themselves.[297] To get a good picture of the IP policies at these organizations, we have been looking at seven universities that incorporate an agricultural and/or plant biotechnology research component,[298] two national research programs,[299] one of the Agricultural Research Service institutes,[300] and the Association of Universities in the Netherlands (VSNU). Amongst these organizations, we have interviewed both researchers and IP managers.[301] Below, we will report on our main findings with respect to the institutional IP policies in place, and other policy matters that impact on opportunities to invest in research for resource-poor farmers in developing countries. Practical issues of IP protection, licensing and transfer will be discussed in the next chapter.

### 5.5.1 Institutional Policies

All the contacted universities have at least one technology transfer office (TTO), either organized at the level of the research departments, or more centrally for the whole university (and medical center, if present). The offices aim to support scientists in the legal and business development activities that come with translating their scientific discoveries into practical and marketable applications, varying from patent applications, out-licensing of patents, setting up spin-off companies, and building relationships with industry through contract research or partnership. Most universities have developed a central IP policy in connection to these offices.[302] Such policies generally deal with issues of authorship, IP ownership and invention disclosure, confidentially and terms for publishing, and the division of costs and revenues.

With respect to ownership of IP, all universities state that in line with Article 12.3 of the National Patent Act 1995 every invention made by an employee is the legal property of the university.[303] In this context, researchers are normally requested to verify whether it is wise to

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297 Research projects involving the private sector, often in the form of public-private partnerships, will be discussed here as well.

298 *Viz.* the universities of Leiden (UL), Utrecht (UU), Groningen (RUG), Wageningen (WUR), Nijmegen (RU) en Amsterdam (VU and UvA).

299 *Viz.* Centre for BioSystems Genomics (CBSG) and Technology Top Institute Green Genetics (TTI GG).

300 *Viz.* Plant Research International (PRI).

301 For reasons of simplicity we refer to IP managers for all persons working in the field of IP management, technology transfer, and knowledge valorization.

302 VSNU 2005. Available at <http://www.vsnu.nl/Media-item/Onderzoek-van-waarde.htm> (accessed on March 16, 2011).

303 Funding agencies such as NWO and STW normally co-own the IP resulting from the research they finance, see section 5.4.

protect their findings before publishing in order to safeguard the possibility of patenting. Yet, as universities consider knowledge dissemination their core task they make sure that in research collaborations with external partners, publications can only be held for a short period of time. Regarding the distribution of costs and revenues, most universities have decided to equally divide net revenues in three between the TTO, the inventors, and the inventors' faculty or research group, subject to varying conditions on, for example, the maximum amounts involved. In return, the research groups must also contribute to the costs involved in patent applications and maintenance.[304]

Few universities also make public notice of their IP policies with respect to research collaborations with external partners and their subsequent position on IP ownership and out-licensing. Utrecht University, for example, states that in collaborations it will maintain the rights to use newly developed IP for "academic and scientific teaching, carrying out academic and scientific research and patient care."[305] Leiden University states that "knowledge which is generated in projects with external parties should at all times remain available for further research and teaching."[306] For that reason, the university applies the principle that such knowledge "remains the property of Leiden University" and affirms that it "does not under normal circumstances meet requests for transfer of such knowledge."[307] An interviewee at Leiden University Research & Innovation Service (LURIS) admits that negotiations with private research partners about IP ownership can be difficult.[308] But also from the side of the government problems may arise, e.g. the new subsidy regulations on valorisation of the Ministry of Economic Affairs (see Box II-10) demands that the IPRs resulting from the financed activities should be transferred to the private sector partners within 30 months.[309] On the other hand, interviewees from both government and industry have indicated that the lack of a clear IP policy at most universities with respect to research partnerships and the out-licensing of IP, impede transparency and complicate negotiations.

### 5.5.2 Drivers for Policymaking

The call for valorisation is clearly the context in which these TTO's and institutional IP policies have arisen. Universities are encouraged to strengthen the ties with private partners in order to promote technology transfer and the application of scientific knowledge into business and society. IPRs are generally considered to play an important role in that process (see Box II-10). Yet, the perspectives on the pros and cons of this development vary considerably among the people interviewed in the course of this project. Opponents either argue that all publicly

304 See *e.g.* <http://www.english.uva.nl/technology-transfer-office/technology-transfer/patents-and-licenses.cfm> (accessed on March 16, 2011).

305 Utrecht University 2010. Available at <http://www.uu.nl/uupublish/content/Uitgangspuntenuuinzake samenwerkingeneng.doc> (accessed on March 16, 2011).

306 Leiden University 2008, p. 18. Available at <http://media.leidenuniv.nl/legacy/instruction%20on%20working%20for%20or%20with%20third%20parties.pdf> (accessed on March 16, 2011).

307 *Idem*.

308 The practical dimensions with respect to the transfer and licensing of IP will be discussed more elaborately in Chapter 6.

309 Regeling tot wijziging van de Subsidieregeling starten, groeien en overdragen van ondernemingen ter invoering van het Valorisatieprogramma 2010, Article 5.2.2.c. Available at <http://www.technopartner.nl/resources/uploads/files/gepubliceerde%20regeling%20stcrt-2010-7633.pdf> (accessed on March 16, 2011).

funded research should be freely available for the benefit of society – including the private sector, or they are of the opinion that universities simply do not have the expertise and infrastructure to exploit IP and deal with business development. In response to the first argument, proponents hold that it is just fair if researchers and universities can share in the revenues that can be derived from their work, and as these revenues are typically reinvested in new research projects, society benefits as well. Most admit, however, that revenue-making is not a straightforward matter. Challenges vary from raising awareness of researchers for the potential commercial value of their work, to developing strategic patent policies and building long-term relations with private partners.

The idea that one can get rich from patenting seems to have disappeared. Apart from some successful examples, most interviewees are well aware of the meager profit perspectives of university patenting and licensing.[310] Yet, the potential for *indirect income generation* is generally considered very important. Indirect income streams can come in the form of public-private partnerships, contract research or the financing of research personnel. An interviewee of the Business Development unit of Wageningen UR Plant Sciences Group stresses the strategic importance of the institute's IP position for acquiring new research contracts and collaborations, especially when big companies are involved (see Chapter 6). But also governmental agencies such as Technology Foundation STW and Agency NL require a strong IP position as a condition for funding.

From the interviews, it transpired that the basic funding for universities (the first flow of funding, see Box II-9) does not provide them with substantial means for doing research. Several researchers who are head of their research group indicated that basic funding only covers their salary and that of one administrative employee. Their group's means for doing research is thus dependent on the income generated from educational activities and designated research grants (second flow of funding), and public-private partnerships, contract research and IPRs (third flow of funding). What further complicates the situation is the demand for *co-matching* of most governmental agencies financing second or third flow research project. This happens in two ways: 1) Both public and private research partners are often required to bring some own money to the table for the start of a new research project,[311] and 2) Funding agencies may finance research personnel while leaving all overhead costs to the participating research organization. This creates problems as most public research organizations generally do not have substantial 'own money'. So next to the national focus on valorisation discussed above, it is also the mere need to generate alternative income streams that prompts universities currently to invest in technology transfer offices and IP policies.

[310] See *e.g.* <http://www.autm.net/Home.htm> (accessed on March 16, 2011).

[311] This has also to do with the strict EU regulations on State Aid, see <http://ec.europa.eu/community_law/state_aids/state_aids_en.htm> (accessed on March 16, 2011).

### 5.5.3 International Development Considerations

With respect to the official IP policies of the public research organizations examined, we did not come across any conditions that refer to the transfer or accessibility of technologies for the benefit of developing countries. Despite the fact that Wageningen UR has no institutional IP policy in place, the director of the Plant Sciences Group (PSG) recently proclaimed that PSG would refrain from patenting any technologies in developing countries.[312] PSG was also the only research group where we came across some applications of humanitarian use clauses in both research and license agreements with third parties.[313] The debate at Wageningen UR on IP protection and the accessibility of technologies for researchers in developing countries was kick-started when an international conference on this specific topic was held in 2008.[314] Where at that time the subject matter was relatively new for most participants,[315] now the internal debate is evolving – to some extent fuelled by the current project - and will probably result in a balanced, institutional IP policy.

Although the official IP policies of the universities do not reveal information on IP management in research collaborations with partners in developing countries, we received some standard research and collaboration agreements from the interviewees. From these, we learned that ownership of intellectual assets that result from the research project (i.e., foreground IP) usually lands with the party who generates the knowledge or invention, under the condition that the other partners are granted a royalty-free, non-exclusive and non-transferrable license to use the findings in the course of the research project.[316] Yet in case the Dutch research organization finances the research project, that organization usually maintains the exclusive right to commercialize and claim ownership over all generated IP. These policies are in accordance with the Dutch Patent Act[317] and the general funding conditions of both Technology Foundation STW and the NWO, with the latter stating that "… the host institution, must ensure in advance that, if any part of the research is to be conducted by individuals who are not employed by the institution, those individuals sign a written statement relinquishing any property rights relating to the results of the research."[318]

Apart from the lack of institutional IP policies that relate to developing countries, few researchers and TT officers reported to have much experience with the development and transfer of technologies to developing countries. Publishing in open source journals and education programs or PhD projects involving students from developing countries were mentioned as the primary instruments to foster development and capacity building in those countries. Yet, the research programs themselves were reported to be mainly tailored towards the needs and interests of the Dutch or 'Western' society. From the interviews we can

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312 Presentation van de Ende at the symposium 'Plantenbiotechnologie in Nederland', 26-08-2010, Wageningen.

313 See for more information Chapter 6.

314 Heselmans *et al.* 2008. Available at <http://www.society-genomics.nl/uploads/media/IP-Policies-Conference-11april2008-Report.pdf> (accessed on March 16, 2011).

315 De Jonge & Louwaars 2009.

316 Background IP – all IP acquired prior to or outside the context of the research collaboration normally stays with the original owner.

317 National Patent Act 1995, Article 12.3.

318 NWO 2007, Article 20; STW demands that "The beneficiary ensures that workers or others who are able to claim rights to the results transfer those rights to the beneficiary and STW." (STW 2009a, Article 7.2)

extract several reasons for this situation, all relating to the current organization and financing of public research in the Netherlands:

1) Apart from few specific funding programs, development issues are not included in the research agenda of the funding agencies;
2) Research must be state of the art and highly innovative to be eligible for funding, which means that applications and adaptations of existing knowledge in order to suit the needs of developing countries do not qualify;
3) There is a strong bias towards research projects and collaborations that aim to support the national private sector in a narrow sense, i.e. without reflecting on opportunities for global development;
4) Most research groups have too little resources to exploit humanitarian opportunities on their own, or to push for the execution of such efforts in research collaborations with the private sector. The latter point may even imply that public research organizations lack sufficient negotiating power to secure the accessibility of new technologies for pro-poor applications in public-private partnerships (see Chapter 6).

According to an interviewee at the Association of Universities in the Netherlands (VSNU), the public research sector does have a responsibility to reflect on these matters but admits that this has hardly happened so far. Recently, however, some discussions have started due to the publication of the internationalization agenda *The Boundless Good* (2009),[319] the report *Less Pretention, More Ambition. Development Aid that Makes a Difference* (2010) of the Dutch Scientific Council for Government Policy (WRR),[320] and the report *Knowledge Without Frontiers* (2010) of the Advisory Council for Science and Technology Policy (AWT). The AWT advises the Dutch government on policy matters in the area of scientific research and technological innovation. Principally, the report recommends to "pursue an internationally-oriented knowledge development and innovation policy," in which one aims to create synergy between the, up till now, organizationally divided worlds of international development policy and knowledge and innovation policy.[321] This entails, as the other recommendations hold, that 1) global challenges should be made a *leitmotiv* for setting the national research and innovation agenda – preferably in connection to areas in which the Netherlands excels and cherishes global ambitions, 2) that research organizations are encouraged to take up these global challenges in cooperation with partners in developing countries, and 3) that new arrangements are to be sought in the fields of intellectual property and the migration of knowledge workers.[322]

With respect to the latter recommendation, it is stated that, "Although developing countries also benefit from IPR, the present system does not provide enough scope for

[319] Internationale positionering van Nederlandse onderwijs- en kennisinstellingen 2009. Available at <http://www.rijksoverheid.nl/documenten-en-publicaties/kamerstukken/2009/10/15/bijlage-a-rapport-internationale-positionering-van-nederlandse-onderwijs-en-kennisinstellingen.html> (accessed on March 16, 2011).

[320] WRR 2010. Available at <http://www.wrr.nl/english/content.jsp?objectid=5190> (accessed on March 16, 2011).

[321] AWT 2010, p. 3. Available at <http://www.awt.nl/uploads/files/Vertalingen/a74.pdf> (accessed on March 16, 2011).

[322] *Idem*, pp. 3 and 4.

knowledge recycling."[323] It is argued that the current system (TRIPS) often creates more barriers than opportunities for developing countries because parties in these countries have very few patents themselves and lack resources to obtain licenses for protected knowledge and innovations from abroad. Also, the need to develop a complex patent system is costly in itself. As an alternative, the authors of this AWT report favor the development of less restrictive regulations (such as Plant Breeder Rights and open source approaches in software) and wonder whether "development policy [should] perhaps play an active or even a leading role when drawing up these regulations?"[324] As a result, the report recommends that "In fields where access to the underlying knowledge is essential from a development point of view, seek options for restricting the protection of intellectual property with respect to this knowledge".[325]

In September 2010, AWT brought together representatives from government, public research institutes, and several non-governmental organizations to discuss the report's recommendations. As all parties seemed to agree with these, the AWT chairman concluded that it is now time to act.[326] Yet, the findings from this research project show that major changes will be needed at all levels of the Dutch research system to turn the above recommendations into practice.

### 5.5.4 Conclusion

In the Netherlands, every invention falls under the legal property of the research organizations where the inventor is employed. Almost all universities have established a central IP policy in connection to Technology Transfer offices. These policies generally spell out the conditions of IP ownership, confidentially and publishing, and the division of costs and revenues. Yet, few universities make public notice of their policies with respect to the ownership and out-licensing of IP in research collaborations with third parties. Although opinions differ about universities protecting and valorising their IP, the importance of IPRs for acquiring research contracts and collaborations is strongly emphasized. This has become an important source of income as public funding and conditions for co-matching leave universities few resources for doing research. International development considerations are, again, lacking from the official IP policies, and we only came across one research group that applied humanitarian use clauses in some of their IP contracts. Furthermore, many interviewees acknowledged that most research is narrowly aimed at our 'Western' needs and interest. The main reasons for this relate to issues of agenda-setting, funding conditions, and the financial organization of public research in the Netherlands. Yet, there are some recent voices calling for a reassessment of this situation, recommending the Dutch government to create synergy between the, until now, separated worlds of knowledge and innovation policy, and international development policy.

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323 *Idem*, p. 31.

324 *Idem*, p. 31.

325 *Idem*, p. 38.

326 See <http://www.awt.nl/?id=692> (accessed on March 16, 2011).

## 5.6 Conclusions

In this chapter, we have analysed how the public agricultural research sector is organized in the Netherlands, what IP laws and policies apply, and how these factors impact upon the room for pro-poor innovation.

Even though Article 66.2 of the WTO TRIPS Agreement prescribes that, "Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members," there is no reference to developing countries in Dutch IP law. The law does provide for different types of compulsory licenses but their conditions make effective use very difficult and no such licenses were granted over the last decades. With respect to governmental policies, the four ministries analysed do not have a coherent IP policy with respect to the research they finance. The Directorate-General of International Cooperation (DGIS) is the only department that in the past utilized an IP policy to secure the availability of IP-protected technologies for humanitarian use. Yet, the need for such policy is not recognized at other ministries. The ministry of Education, Culture and Science (OCW), which is responsible for about two-thirds of the research funding, strongly opposes a central IP policy as it considers this the responsibility of the sector itself and because it values the sector's autonomy.

It appeared that valorisation, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is the primary driver for IP policymaking in the public research system in the Netherlands. This is, for example, reflected in the IP policies of most funding agencies, which emphasize the need for IP protection as a necessary means to trigger private investments and technology transfer from the public to the private sector. International development considerations do not feature in the policies of these funding agencies, and IP tools such as humanitarian licensing are not used. Yet, the Netherlands Organization for Scientific Research (NWO) has recently established an Incentive Fund for Open Access Publications, which can improve global access to Dutch scientific knowledge.

The call for valorisation is also the main context in which public research organizations have started to develop institutional IP policies in close connection to technology transfer offices. Furthermore, several research and IP managers at these institutions indicate that the current financing structure forces them to develop alternative income streams, and one's IP portfolio is considered very important for acquiring research contracts and collaborations with the private sector, in particular with large corporations. In addition, several funding agencies require a strong IP position as a condition for research funding. Again, we did not come across any conditions or references to the accessibility of IPRs in relation to developing countries within the institutional IP policies examined, and we found only one research group employing humanitarian use clauses in some of its contracts with third parties.

Most researchers reported to have little resources and incentives for pro-poor innovation and technology transfer due to the current organization of public research in the Netherlands. Major causes are the research financing system and regulations concerning co-matching, which leave public research organizations little room to invest in, or secure the availability of their IP for development applications. Moreover, most research funding is targeted at highly innovative technologies and research projects that are narrowly aimed at 'Western' needs and interests. In this way, opportunities for global development or the

adaptation of existing knowledge to suit the needs of developing countries are left out, leaving development issues to be addressed by only a few specific funding programs.

Overall, it has become clear that research and innovation policy on the one hand, and international development policy on the other, are currently organized and perceived as two worlds apart. Yet, there are some recent voices calling for a reassessment of this situation, recommending the Dutch government to create more synergy between the two policy fields. Given the current situation, however, this will require a *paradigm shift* on all levels of the Dutch research system. Next to different agenda-setting, funding policies, and valorisation targets that reach across borders, new arrangements in the field of IP protection will have to be developed that facilitate international collaborations and secure the availability of research results for development purposes.

# CHAPTER 6 IP PRACTICES IN THE NETHERLANDS: IPRS AND TECHNOLOGY TRANSFER TO DEVELOPING COUNTRIES

*Bram De Jonge & Niels Louwaars*

**Abstract**
This chapter analyzes the effects IPRs have on the accessibility and transfer of research materials within the Dutch agricultural research sector, and with respect to four research projects that aim specifically at transferring agricultural technologies to developing countries. Ultimately, the positive and negative roles of IPRs are assessed, also in relation to non-IP factors. We found that most research materials (also when protected by IPRs) are still freely exchanged without serious delays. Public research can, however, be seriously thwarted due to the restrictive licensing conditions of some companies and the weak research exemption in the Dutch Patent Act. The importance of having freedom to operate is also illustrated by the current patents vs. Plant Breeder's Rights debate, with opponents of the current patent system warning that patents pertaining to plant varieties hamper further breeding and, thus, food security. The case studies illustrate that humanitarian projects, which aim to develop improved seeds for resource-poor farmers (something that goes beyond the standard permissions in material transfer agreements), can face serious transaction costs and legal uncertainties due to third-party IP. Furthermore, the idea that humanitarian licenses can negatively affect one's own interests appears to be widespread in the Dutch agricultural research system. Yet, the case studies also show that IPRs are not the only, and not necessarily the most important, stumbling block to technology transfer in research for development, especially when GM technologies are concerned.

## 6.1 Introduction

In this and the previous Chapter, we discuss the IP policies, practices, and perceptions of the main actors in the Dutch agricultural research system in the context of our central research question: What is the role of IPRs in the management and sharing of knowledge for development (the achievement of MDG 1c). Our objective is to investigate how IPRs affect the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries. Whereas the previous chapter zoomed in on the policy level, this chapter focuses on the *practices* of IP protection, licensing, and the transfer of research materials. First, we will analyze the effects IPRs have on the accessibility and transfer of research materials within the agricultural research sector. This will be done by collecting the experiences from several high-level research and IP managers from both the public and private sector. Then, we study the use and management of IPRs in four case studies that aim specifically at transferring agricultural technologies to developing countries. Finally, we will assess the positive and negative roles of IPRs for pro-poor innovation. Hereby, we will not only discuss the problems and opportunities that IPRs can create, but also reflect on the

relative importance of IPRs vis-à-vis non-IP issues.[327]

### 6.2 Experiences with accessing and transferring research materials and IPRs

To analyze the effects IPRs have on the accessibility and transfer of research materials, we have interviewed research and IP managers from both public organizations and companies active in the Dutch agricultural research sector. In this section, we will first report on the experiences and perspectives of public researchers and their IP managers,[328] followed by representatives from industry. Hereby, we discuss particularly the use and in-licensing of third party IP. In the next section, the focus will be on out-licensing and the transfer of agricultural technologies to developing countries.

#### 6.2.1 Experiences of Public Researchers

The public researchers interviewed, all heads of their research groups with longstanding experience, indicated that the number of patent applications in their name do not reach double digits. Researchers involved in fundamental research on model organisms indicated that IPRs do not play a major role in their work, while those working in more applied research fields and in public-private partnerships typically have more to do with IPRs. Yet, all interviewees indicate that most research materials are still freely exchanged, either with or without a Material Transfer Agreement (MTA) attached. Such research and development license may demand that the provider of the material is appropriately referred to in publications and product information that relate to that material. In case of (potential) commercial value of the material, the MTA commonly addresses issues of ownership and commercialization, often setting conditions on further use and the transfer of the material to third parties (see Box II-14). Even though such agreements are normally dealt with by the universities' legal offices, no serious delays in the transfer of research materials were reported by the interviewees as a result of the screening those agreements go through.

**Box II-14:** ***MTA Conditions of EP Patent 0176112, US Patent 4.940.838.***

*The first, and one of the most successful, university patents in plant biotechnology in the Netherlands was a patent on the process of incorporating foreign DNA into the genome of dicotyledonous plants by use of the soil bacterium Agrobacterium tumefaciens. This invention, whose patent was filed in 1983 by three researchers from Leiden University,[329] is globally used for the genetic modification of plants. The patent was first licensed exclusively and later sold to Mogen, a Dutch biotechnology company that was acquired by Zeneca (now Syngenta) in 1997. Yet, the inventors maintained the right to freely exchange the patented technology and material to colleagues for research purposes under the following MTA conditions:*

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327 Input for these analyses in this and the previous chapter is derived from literature studies and semi-structured interviews with those responsible for IP and agricultural research at ministries (no. of people interviewed: **7**); funding agencies (**5**); national research programs (**2**); researchers (**12**) and IP officers (**7**) at public research organizations; the private sector (**7**); and science interest/advisory organizations (**4**).

328 For reasons of simplicity we will refer to IP managers for all persons working in the field of IP management, technology transfer, and knowledge valorization.

329 Schilperoort, Hoekema and Hooykaas 1983.

*I state that the supplied materials or derivatives thereof will exclusively and restrictedly be used in my laboratory for fundamental research and under suitable containment conditions.*

*I state that the supplied materials will not be used in production or commercial applications (including contract research) or for patent purposes.*

*I state that the supplied materials will not be given out to other laboratories, institutions or companies either within or outside my institution.*

*I state that the source of the supplied materials will be acknowledged or properly referred to in publications.*

Some national and international biotechnology companies, however, apply such restrictive conditions in their MTAs that several interviewees indicated not to use that material in their research programs. In these MTAs, the user has to agree that all derivative inventions and materials that result from doing research on or with the provided technology are not only available for use by the provider, but the provider also maintains the right to claim IP protection over them. So, by using the knowledge, technology or material provided under such MTAs, any kind of additional invention in any area would fall under ownership of the providing party. Such conditions - together with a weak research exemption, can seriously impede public sector research with commercially developed technologies.[330]

This is particularly the case with respect to genetic modification (GM) technologies. In 2009, a group of 26 researchers from several US universities lodged an anonymous public complaint stating that "No truly independent research can be legally conducted on many critical questions involving [commercial biotech crops]", because of "company-imposed restrictions".[331] Since almost all GM crops are developed by commercial entities, which carefully control the rights over their proprietary technologies, they are the ones "to decide who studies the crops and how."[332] Consequently, public researchers must ask permission to the technology holder for each project, usually by describing in detail what the research will be about. In response to the above public complaint, several biotech companies have started to negotiate umbrella licenses with universities in order to develop general agreements on research terms and permissions with respect to their crops. Although a first blanket agreement with Monsanto was positively received, it only allows researchers to conduct agronomic research ("studies on how crops interact with local environments and which varieties perform best"), and no breeding, reverse engineering, or studies on the genetic composition of a crop, amongst others.[333]

Despite the fact that some companies are very strict on the use of their IP, none of the researchers reported to have been subject to explicit controls or claims with respect to the use of third party IP or compliance with MTA conditions. In this context, some researchers reported to check their 'freedom to operate' before starting a new research project, mainly because funding agencies or private partners demand this, but also to keep open future possibilities for patenting and knowledge exploitation. Others, however, indicated seldom or never checking for such rights as they consider this unnecessary for their type of research (fundamental) or because they lack time and expertise to delve into patent databases. Those

330 Another effect of these restrictive conditions can be the public subsidizing of private research.

331 Waltz 2009, p. 880.

332 *Idem*.

333 Waltz 2010, p. 996.

that have some experience with patent searches also reported that due to the large number of patents and the complexity involved (e.g., patents with apparently very broad claims), one cannot do much research without running into third party IP.

The research exemption was also repeatedly mentioned as a reason not to worry about third party IP. Yet, this may not always be supported by the legal extent of that exemption in Dutch law.[334] Consequently, a technology transfer expert indicated that this is very risky, especially because commercial parties tend to direct their infringement claims to "the deepest pockets" – the large enterprises. Since several universities are quite rich (in terms of real estate) they might become the target of rent-seekers when they are too relaxed with the research exemption. The main reason not to sue universities is – according to this spokesman, that such actions could create negative publicity.

### 6.2.2 Experiences of IP Managers at Public Research Organizations

One of the challenges of IP managers at public research organizations is to make researchers more aware of the importance of taking care of their and others' intellectual assets. Another challenge is to negotiate the conditions for use and transfer of such assets in research collaborations with private partners. Even though few universities make public notice of the position they take in such negotiations (see chapter 5), it transpired from the interviews that freedom to operate, i.e. freedom to use all knowledge and materials resulting from research for or with private partners for further research and education, is generally considered a *sine qua non*. Everything else is up for negotiation. Key issues that have to be discussed in most research contracts concern the designation of background and foreground IP, the division of rights and duties with respect to this IP, and the rules for transferring IP rights between partners or to third parties.[335]

Such negotiations are seldom easy and clear-cut. Take for example the issue of ownership of IP. Leiden University normally aims to retain the IPRs that result from research partnerships and to issue licenses to the research partners involved.[336] In this way, the university can remain in control of the IPRs and, thus, their freedom to operate. Ownership rights are legally stronger than rights assigned by contract because in the latter only the contract parties are bound, whereas IPRs affect all potential users, e.g., the university might lose control over its technology in case a company that owns the IPRs involved goes bankrupt. Another reason for this strategy is that the university can license a technology to several companies operating in different markets in order to stimulate the wider application of their research results. Many companies, however, do not favor such agreement because they want to be in control of the IPRs themselves, often for strategic reasons but also to be sure that the IPRs are properly managed, e.g. that patent maintenance fees are paid in time, and infringements controlled.

Who gets the IP rights depends heavily on the relative contributions, in cash and in kind, of the different research partners and on their negotiation capabilities. Yet, the costs of IP protection also play an important role in the negotiations about the ownership and licenses of

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334 See Chapter 5, section 5.2.

335 See *e.g.* TTI GG 2008. Available at <http://www.groenegenetica.nl/pro1/general/start.asp? i=0&j=0&k=0&p=0&itemid=72> (accessed on March 16, 2011).

336 Leiden University 2008. Available at <http://media.leidenuniv.nl/legacy/instruction% 20on%20working%20for%20or%20with%20third%20parties.pdf> (accessed on March 16, 2011).

IPRs between public and private research partners. Several IP managers indicated that they, in spite of the above reasons to keep IPRs in one's own hands, have to limit the number of patents that are (co-)owned by the university because of the costs involved. As a consequence, most patents must as a rule of thumb be transferred or withdrawn within 30 months of their filing date because then the costs rise substantially (see Box II-15 ).

**Box II-15:** ***Costs of Patenting***

*Asking how much a patent costs is like asking how much a house or a car costs. It strongly depends on what is patented (the complexity of the invention) and where. The Dutch Patent Office estimates the price of an application for a European patent between 25,000 and 50,000 euro.*[337] *These are application costs over the first three years and include the hiring of a patent attorney to draft the patent, the filing fees, and an international novelty search. When a European patent is granted, the applicant has to decide in which of the European countries the patent will be registered. That decision greatly affects the costs as currently the patent must still be translated into all the languages of the countries in which it is being pursued. Additionally, maintenance fees must be paid separately in each country. When following the Patent Cooperation Treaty (PCT) procedure, the applicant has maximally 30 months to decide in which countries in the world the patent rights will be established.*[338] *From that moment, total costs can go over 100,000 euro when the patent is registered in both Europe and the US. This is especially the case for biotechnology patents, which, due to their complexity, can cost twice as much as a patent in electrical engineering.*[339] *Next to these filing and maintenance costs, one should take into account potential enforcement costs in case of patent infringement, which may run into the millions.*

Not all industry representatives are happy about universities building a patent portfolio. To some, public research organizations should focus on scientific excellence and leave matters of IP protection to the private sector. Both opponents and proponents, however, emphasized that the road from a patented technology to a marketable product is very long and involves many risks and major investments, which means that the commercial value of a university patent is easily overestimated.[340] Another issue mentioned by most industry representatives is that they have no problem with universities doing research on and with technologies that are patented by their company as long as the university does not behave as a competitor in the market. Yet, this situation might be different in the US, where public researchers have been complaining about the company-imposed restrictions to do research on commercial GM crops.[341]

337 See <http://en.octrooicentrum.nl/patents-application/in-europe.html> (accessed on March 16, 2011).

338 WIPO 2010. Available at <http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (accessed on March 16, 2011).

339 EPO 2010. Available at <http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf> (accessed on March 16, 2011).

340 See *e.g.* Heimovaara 2010. Available at <http://www.dafne-entrepreneurship.nl/Pages/TT.aspx> (accessed on March 16, 2011).

341 Waltz 2009.

But according to the university's IP mangers, IPRs have simply become "part of the game"[342] due to the present-day environment in which their organizations have to operate. As we have seen in the previous chapter, the Dutch government strongly supports public-private partnerships, and contract research has become an important source of income for public research organizations. Hereby, IPRs do play an important role as most funding agencies demand a strong IP position as a precondition for research funding, and several IP managers reported that their IP portfolio is indispensable for attracting research contracts and partnerships, especially where multinational companies are concerned.

The conditions for accessing IPRs filed by public research organizations depend heavily on the context in which the technologies were developed. Interviewees at Wageningen UR indicated that IPRs resulting from 100% publicly funded research will only be available under non-exclusive licenses so that their availability is secured for all interested parties. Yet, many IPRs result from public-private partnerships, which means that the technology's availability depends on the conditions for access as agreed by the different research partners. This commonly leads to more exclusive outcomes, since a company contributing to the research project gets, usually, at least a right of first refusal to obtain a (non-)exclusive license for the technology in question, or an advantage of some years that information and materials will be withheld from others. However, *transparency* on these issues is still lacking for researchers, private partners and the general public alike, due to the absence of a clear IP and licensing policy with respect to research partnerships at most universities.[343]

### 6.2.3 Experiences of Private Sector Representatives

From the private sector we received diverging messages, which strongly relate to the current debate, both in the Netherlands as internationally, on 'patents versus Plant Breeder's Rights'. The plant breeding companies that oppose patenting in favor of Plant Breeder's Rights emphasize that patents pertaining to plant varieties seriously hamper the accessibility of these varieties for further breeding. Plant Breeder's Rights, on the other hand, allow breeders to use protected varieties for the development and exploitation of new varieties through the so-called breeders' exemption. Because the breeding of new plant varieties has and will always depend on crossbreeding with existing varieties or exotic materials with specific genetic traits, the continued accessibility of these building blocks is considered absolutely essential for further innovation in the sector. For that matter, the significant increase in plant-related patents over the last decades is considered to "have serious consequences for most plant breeding companies and the subsequent links in the food chain, right up to the consumer."[344]

In 2009, the ministries of Agriculture, Nature and Food Quality and of Economic Affairs[345] commissioned a study on the future of plant breeding in light of developments in

342 De Jonge 2008.

343 See Chapter 5.

344 Plantum NL 2009, p. 7. Available at <http://www.plantum.nl/plantum/documenten/Standpunt%20Octrooi%20en%20Kwekersrecht%20volledig%20ENG.pdf> (accessed on March 16, 2011). Plantum does not oppose patents per se: It supports patents on innovative processes and techniques, for which use a license is required. Yet, varieties that have been developed using a patented process should, again, be freely available for further breeding.

345 Since the inauguration of the new government in October 2010, the ministry for Economic affairs,

patent law and plant breeders rights (see Box II-8). This study confirms that patent positions in combination with technological developments and globalization trends have led to considerable consolidation in the sector, with only few companies controlling a major part of the world market for most major crops.[346] And it concludes that "access to genetic variation is so crucial for further innovation in breeding that a form of breeder's exemption within patent rights is required."[347] Furthermore, it recommends that if a diversified seed sector with full competition among larger and smaller companies is to be aimed at, strategic patenting (see Box II-16) has to be curtailed (by the industry itself) and patent quality is to be vigorously increased (by the patent offices).

**Box II-16: *Strategic Patenting***

*Strategic patenting is the deployment of the patent system to primarily serve strategic objectives rather than commercializing the very invention that is protected. In the extreme case it is applying for patents with the only objective to block competitors in the market or in a research area. This can for example be done by building 'patent thickets', i.e., "a dense web of overlapping Intellectual Property Rights that a company must hack its way through in order to actually commercialize new technology."[348] The overlapping patents make it very difficult or even impossible for others to assess the precise boundaries of claims and, thus, to determine how far protection is reaching. An even more offensive strategy is to patent inventions that are similar, but not identical, to the invention that one aims to commercialize in order to prevent others from commercializing competing products.[349]*

The Dutch breeders association Plantum NL formulates the unwanted consequences of plant-related patents as follows:

> "First and foremost, we can expect a price increase for plant propagating material, since any costs which are associated with obtaining licenses and applying for or defending patents will be passed on to the growers. Not all plant breeding companies will be able to obtain licenses for important traits, as a result of which the growers will be faced with a more limited choice between the different suppliers of a particular crop. Finally, the expectation is that there will be even more consolidation as some plant breeding companies will no longer be able to maintain a competitive position in the market. This lack of players keeping up the competitive pressure will slow down the level of innovation in general across the sector."[350]

Ultimately, these consequences are considered to negatively affect global food security as "world food supply benefits when there is sufficient competition between the plant breeding companies and when open innovation is preserved."[351]

It must be acknowledged that the companies opposing the current patent system are

Agriculture and Innovation (EL&I).

346 Louwaars *et al.* 2009, pp. 24-28.

347 *Idem,* p. 53.

348 Shapiro 2001.

349 Blind, Cremers & Mueller 2009.

350 Plantum NL 2009, p. 7.

351 *Idem*, p. 8.

using that system themselves in order to currently secure their position in the market. Similarly, they demand strong IP protection of, and negotiate for their rights on, valuable assets that result from collaborative research projects with the public sector. The reason for this is that these companies, in their competition with others, cannot choose to apply a different set of rules unilaterally. They have to stick to the current rules of the game in order to protect their position, but they explicitly state that they favor a radical change of the present IP system.[352]

Opponents of the Plantum NL standpoint indicate that it is already becoming more difficult to file plant biotech patents. Recent court cases in the US and Europe show that the granting of patents is being tightened[353] and the European Patent Office is taking steps to improve patent quality through its 'raising the bar' initiative.[354] With regard to strategic patenting it is argued that problems result from patenting and licensing practices and not the patent law itself. So instead of changing the system, these problems should be solved by the different actors within the sector itself. Finally, it is remarked that opposition to the patent system is merely a result of inexperience and lack of knowledge of the system by smaller companies.

The proponents of the patent system emphasize that patents – as the strongest form of intellectual property protection, are indispensable for innovation.[355] Research and development in biotechnology involve huge investments, which can only be recovered when inventions can be properly protected. For that purpose, and because many biotechnologies are easy to copy, it is argued that patents and Plant Breeder's Rights should be considered supplementary protection tools that protect different aspects of plant research and innovation.[356] Furthermore, the Plantum NL standpoint to include a full breeders' exemption in patent law would require an amendment of the EU Biotechnology Directive 98/44.[357] Opening up this directive may lead to long-lasting debates featuring all kinds of social sentiments (e.g., about GMOs, the patenting of living organisms, stem cell research) that, as argued, have nothing to do with the protection of intellectual property *per se*. Such debates will create uncertainty, affecting many industries beyond the plant breeding sector and stifling investments and, thus, innovation across the board.

As an alternative, CropLife International – a federation representing the major agro-biotechnology companies,[358] proposes a "balanced breeders' exemption", which entails that:

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352 See *e.g.* Tax 2010.

353 See Chapter 1, box 1.1.

354 See <http://www.epo.org/about-us/office/annual-report/2007/focus.html> (accessed on March 16, 2011).

355 NIABA 2010. Available at <http://www.niaba.nl/website/wp-content/uploads/2010/02/BRF-Verburg-22-juni-DEF.pdf> (accessed on March 16, 2011).

356 CropLife International 2009. Available at <http://vorige.nrc.nl/multimedia/archive/00242/Patentrecht_09-06-2_242607a.pdf> (accessed on March 16, 2011).

357 Plantum NL 2010. Available at <http://www.plantum.nl/plantum/persberichten/10-04-20.pdf> (accessed on March 16, 2011).

358 See <http://www.croplife.org/> (accessed on March 16, 2011).

> "…breeders may freely, without a license, use germplasm containing PTT [patented trait technology] for developing and commercializing a new variety *that does not contain the PTT* under the conditions that 1) the PTT-containing material is discarded as soon as practically possible and in compliance with all applicable laws and regulations and 2) continued breeding occurs only with PTT-free germplasm."[359]

In this way, CropLife aims to prevent restrictions on the use of the "germplasm base" necessary for further breeding while at the same time protecting all rights of a patentee to his or her invention.

It is clear that the current debate on patents vs. Plant Breeder's Rights entails strongly opposing viewpoints on the importance of patents for innovation in the plant sciences industry. Yet, all agree that patents affect the *accessibility* of technologies and genetic material for further breeding and commercialization, both in developed and developing countries. The pro-patent camp, obviously, does not consider this a problem. One of the arguments to support their case is that breeders in countries without a breeders' exemption in their patent law, like the US, are amongst the most successful in the world.[360] Advocates from the pro-PBR camp, on their turn, emphasize the anti-innovative effects of the current patent system. A lawyer from seed producer Limagrain, for example, testified that he had to stop researchers in his company in many cases from exploring new things because of IP rights granted to seed material.[361] These conflicting arguments make it difficult to come to one overarching conclusion, and they warrant further research on the subject. Yet, the observation that the current system is especially challenging for smaller companies[362] demands that the issue is taken seriously into account when discussing the impact of IPRs on developing countries. In section 6.4 we will look more specifically at the relevance of this debate for developing countries.

### 6.2.4 Conclusion

The public researchers indicated that most research knowledge, technologies and materials are still freely exchanged without serious delays. Yet, some companies were reported to include such restrictive Material Transfer Agreement conditions that the researchers preferred not to work with those materials. Together with the weak research exemption in the Dutch Patent Act, this can thwart public research on commercially developed technologies, as in the case of GM crops. The IP managers reported that the freedom to use all knowledge, technologies and materials, resulting from contract research or research partnerships, for further research and education, is generally considered a *sine qua non* in negotiations with third parties. Yet, the one who gets the IP rights depends heavily on the relative contributions, in cash and in kind, of the different public and private research partners and on their negotiation capabilities. The outcome of this strongly affects the conditions for access, and only the IPRs resulting from 100% public funds were guaranteed to be available under non-exclusive licenses. Yet, transparency on these issues is still lacking due to the

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359 CropLife International 2009, p. 3. Emphasis in original.

360 *Idem*, p. 1.

361 Intellectual Property Watch 2010. Available at <http://www.ip-watch.org/weblog/2010/07/21/international-experts-see-backswing-in-pendulum-of-biological-patenting/> (accessed on March 16, 2011).

362 Louwaars *et al.* 2009, pp. 51-52.

absence of a clear IP policy with respect to research partnerships at most universities. The industry representatives are particularly concerned about the current patent vs. Plant Breeder's Rights debate, and they have strongly diverging views on the pros and cons of including some breeder's exemption in patent laws. Whereas especially the largest multinational companies emphasize the importance of strong IP protection for stimulating innovation in the plant sciences industry, many of the smaller companies, also multinationals, warn that patents pertaining to plant varieties hamper further breeding and, thus, food security.

## 6.3 Technology Transfer to Developing Countries: Four Case Studies

Whereas the previous section discussed the use and in-licensing of third-party IP, this section focuses on the out-licensing of IP for development purposes. For that purpose, we looked for research projects (primarily) based in the Netherlands that aim at promoting technology transfer to developing countries. In total, we came across four cases in which IP issues play an important role.[363] These cases concern four different crops (shallot, cassava, potato and vegetable Brassica, respectively), but all involve the application of genetic engineering technologies. In three of the four cases, specific IP mechanisms and strategies are applied to facilitate the transfer of protected technologies to developing countries. For each case, we will analyze the various issues that surround the use and management of IPRs, and indicate the relative importance of these IP issues for the success or failure of the project vis-à-vis non-IP factors.

### 6.3.1 Shallot Case

The first case study took place in the context the Biotechnology, Plant Breeding and Seed Technology for Horticulture (BIOBREES) program, which started in 1994 as a collaboration between the Dutch and Indonesian ministries of agriculture.[364] Hereby, the Dutch ministry provided the research funds (0.9 million Dutch Guilders per year) matched by the Indonesian ministry with in-kind contributions. The program included horticultural research whereby "priorities were set with the interest of both sides in mind, and the outcome would be jointly owned."[365] Despite this objective, the program started without a specific strategy on the use and management of the IPRs involved. One of the projects aimed at developing shallots[366] that are resistant to the beet armyworm[367] through both conventional and transgenic breeding, executed at Wageningen UR and Bogor Agricultural University.

Shallots are an important vegetable crop in Asia, grown at 90,000 hectares in Java alone, especially by smallholder farmers. The beet armyworm is a major hazard to the production of shallot with yield losses up to 70%.[368] Insecticides are widely used, causing

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363 For example, a project concerning the transfer of hybrid tomato seeds to small-holder farmers in Latin-America was not selected as IPRs did not feature as a major issue.

364 *I.e.* the Dutch Ministry for Agriculture, Nature and Food Quality (LNV), and the Indonesian Agency for Agricultural Research and Development (AARD).

365 Burg 2003, p. 3.

366 *Allium cepa* L.

367 *Spodoptera exigua* Hübner.

368 Zheng 2000.

serious threats to the environment and the health of farmers and consumers, and increasing production costs. Furthermore, they are far from adequate because the beet armyworm larvae protect themselves by webbing and because of reported insecticide resistance.[369] Since genetic resistance was found neither in the crop nor in its wild relatives, efforts were started to develop a transgenic shallot by using genes from the bacterium *Bacillus thuringiensis* (Bt). Early 2000, a transformation protocol was developed, Bt genes were successfully transferred and the resulting Bt-shallots were found resistant to the beet armyworm.[370] These were then crossed with several local varieties, ready to be tested in the field.

One of the used constructs carried the *Ho4* Bt gene, which had been supplied by Syngenta under a research license.[371] This implied that although the technology could be freely used for research purposes, further negotiation would have to follow once the technology was to be used in Bt-shallot varieties in the field. Also, Seminis Vegetable Seeds, today part of Monsanto, holds the IP rights over a method for transforming Allium species that was used. Yet, when Wageningen UR contacted Seminis/Monsanto to inform about the conditions for use, no reply was received. This is not uncommon when a company has no commercial interest. Spending time to negotiate use in small vegetable crops, and a potential market composed of small-holder farmers in developing countries, may be considered a bad investment. Yet, for the public research organizations such non-reply creates uncertainty as the IP holder can block the use of its technology at any moment. Furthermore, uncertainty about the freedom to operate can affect the willingness of other parties to join the project.

This became apparent when Wageningen UR started to look for a private partner that would be interested to take the technology further. As the next stage of the research project was to test the modified shallots in the farmers' habitat, the Bt-shallots had to go through the biosafety regulations, since Indonesia had established a national biosafety policy in the late 1990s, and ratified the Cartagena Protocol in 2004.[372] Because none of the public partners had the money and expertise to enter into the regulatory process that comes with the field testing of genetically modified organisms, Wageningen UR contacted several vegetable breeding companies whether they would be interested to join the project and take the Bt-shallots to the market.

In a letter to the vegetable breeding companies, it was stated that IP ownership over the material developed would initially stay with Wageningen UR, but could be transferred or licensed to the interested company at a later stage. Wageningen UR also performed an IP search on all the varieties, genes, regulatory sequences and methods used in the research project in order to assess third-party IP. From this, it appeared that about 15 patents and 2 PBRs were involved. Some of these patents were soon to be expired, or would only be infringed upon export to the US. Other gave rise to some uncertainties (e.g., with respect to the status of the patent or the reach of its claims), and for a few a license was to be negotiated (amongst which the Syngenta and Monsanto IP mentioned above). All these matters were left to the company that would eventually market the Bt-shallots.

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369 Zheng *et al.* 2005.

370 *Idem*.

371 *Idem*.

372 Ministry of Environment of the Republic of Indonesia and UNEP-GEF 2004. Available at <http://www.unep.org/biosafety/files/IDNBFrep.pdf> (accessed on March 16, 2011).

Yet, no company was interested to take the Bt-shallots through the deregulation trajectory with an estimated cost of about six to ten million Euros.[373] This was not considered economically feasible given the low profit margins for this crop and the third-party IP involved. Furthermore, the Dutch vegetable breeding companies were hesitant to get involved with a GM crop because of the public controversy surrounding that technology. So, even though the Bt-shallots had been developed and showed good resistance to the beet armyworm in the laboratory,[374] the technology has never been implemented. This to the frustration of the researchers involved. Wageningen UR maintained the Bt-varieties for some time in confined greenhouses, but this was stopped due to the costs involved and without a prospect for future use. Now, only the seed are kept in storage.

### 6.3.2 Cassava Case

The next three cases involve various IP strategies that aim to facilitate technology transfer to developing countries. One IP mechanism that can be used to secure the availability of technologies for use in pro-poor research is a *humanitarian use license* (see Box II-11). Several examples have been applied by the Plant Sciences Group at Wageningen UR in research contracts and IPR licenses. The first example in 1997 arose when researchers at Wageningen UR were involved in the Cassava Biotechnology Network, funded by the Dutch Directorate-General of International Cooperation (DGIS).

In the 1990s, research subsidies by DGIS were subject to the condition that the department would co-own any IP resulting from the research carried out and, thus, that it could co-decide on its use (see Chapter 5). At some point, a method for producing and transforming cassava protoplasts was developed, which was also of interest to private company Avebe, which specialized in the production of potato starch for food and non-food industries.[375] After negotiations with Wageningen UR, the technology was put at the company's disposal and they filed a patent in 1996.[376] Yet, DGIS demanded that the technology would stay available for humanitarian use. This led to a license agreement between the three parties in which the company grants DGIS "the right to apply the technology within the framework of development cooperation as well as the right to make the technology available to foreign institutions for aid to developing countries."[377] Yet, if the transfer of this technology could reasonably lead to competition for Avebe in the area of modification of starch, DGIS would have to consult the company beforehand.[378] In practice, this means that the technology could be used royalty-free for food security goals and local or national use, but not for the global starch trade. From the people involved we learned that such humanitarian license with 'field of use restriction' was a novelty at all three organizations, which meant that it took some time before a suitable agreement text was drafted.

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373 This estimate corresponds with the outcomes of a scientific study that calculated the compliance costs for regulatory approval of a new biotech crop in both the US and EU between 3.7 – 10.3 million € (COGEM 2008). Kalaitzandonakes *et al.* 2007 calculated 'slightly' lower costs (4.2 – 9.4 million € for ten countries).

374 A reason why the project was advertised as a big success, see *e.g.* Burg 2003.

375 See <http://www.avebe.com/AboutAVEBE.aspx> (accessed on March 16, 2011).

376 AVEBE *et al.* 1996.

377 License agreement [not public], Article 2 (translated).

378 *Idem*, Article 3.

After the agreement was signed and with the extra money received from Avebe, the Wageningen researchers developed transgenic cassava varieties that have been planted in field trials in Indonesia and the Virgin Islands. For some years, this was also tried in South Africa but that country did not authorize the field trials. Due to both agronomic reasons and the high costs of getting regulatory approval to cultivate the GM crop, the cassava varieties never reached the market.

According to the research manager and TT officer involved, Wageningen UR aims to include such licenses in IPR agreements with third parties more often but it appears difficult to materialize. The main reason is that most research takes place in public-private partnerships, where the humanitarian license issue has to be brought to the table by either party and accepted by all. If one research partner is not interested in the inclusion of such license, it may lead to a lower license fee, something that cash strapped public research organizations in practice do not prefer. Interviewees from both the public and private sectors indicate that many companies have reservations with respect to the application of humanitarian licenses because of the uncertainties that come with it. Doubts are especially created by the risk that protected technologies, which were provided royalty free for humanitarian purposes to a specific party or region, end up in a competitive product in the market. To others, this worry is unfounded as you can carefully spell these issues out in the humanitarian license. Still, the question is how such licenses, and compliance with their terms, can properly be controlled.

### 6.3.3 Potato Case

The effort required to balance the different interests can well be described by looking at the potato research at Wageningen UR. Potato is among the most important arable crops grown in the Netherlands.[379] Yet, because of fungus threats, especially late blight (*Phytophthora infestans*), the potato is also the most sprayed crop in the Netherlands, responsible for about 80% of fungicide use[380], amounting to an estimated annual cost of €133 million.[381] For these reasons, the ministry for Agriculture, Nature and Food Quality (LNV) finances several research projects with the aim to develop a late blight resistant potato. These projects often take place in close collaboration with private potato breeders.

In 2006, the ministry provided Wageningen UR with € 9.9 million for a 10-year project on Durable Resistance against Phytophthora (DuRPh), which aims to develop potato varieties with a durable and high level resistance against late blight using cisgenesis (see Box II-17). The project results are expected to reduce production costs and health and environmental burdens, and to help to maintain the competitive abilities and employment in the Dutch seed potato production sector.[382] Yet, as late blight is also a threat to the food security of millions of people in the developing world who rely on potato as a staple crop, the ministry prompted the researchers at Wageningen UR to also look at possible applications in these countries. In 2009, this resulted in Wageningen UR signing a Letter of Intent with the International Potato

379 Annually, about 75 000 hectares of ware potatoes (mainly used for the production of chips and crisps), 50 000 hectares of starch potatoes and 40 000 hectares of seed potatoes are grown, of which the majority is exported. With a yield of 45 tons per hectare, this amounts to a produce of about €800 million worth (Projectgroep DuRPh 2008, p. 9-10).

380 LNV 2006.

381 Projectgroep DuRPh 2008, p. 12.

382 See <http://www.durph.wur.nl/UK/> (accessed on March 16, 2011).

Centre (CIP) and Cornell University to join forces in order to develop cisgenic late blight resistant potatoes for the benefit of the resource poor.[383]

**Box II-17: *Cisgenesis***

*Cisgenesis is a genetic modification (GM) technology that only makes use of genetic material from the same species and its crossable wild relatives. This distinguishes it from transgenic GM technologies that work with transgenes – i.e., synthetic genes or genes from non-crossable species. Conventional potato breeding is very time consuming because crossing creates an enormous diversity which makes it very difficult to align preferred genes in one clone. This is even more difficult when genes from distant (wild) sources are to be used and many unwanted genes have to be removed by means of repeated backcrossing. With cisgenesis, only the relevant resistance genes are inserted into existing varieties.*
*As the technology does not involve 'foreign genes' and basically creates varieties that could also have been obtained through crossing, repeated backcrossing and selection, the researchers hope that cisgenesis will not cause public controversy the way transgenic GMOs have . Furthermore, they argue for a cheaper and faster approval trajectory for cisgenic varieties.[384] This is considered important since current biosafety regulations are very time-consuming and expensive for public institutions and small or medium-sized enterprises serving niche markets and crops.*

In the letter of intent, the three parties invite public research organizations in developing countries to join the project. Currently, the first meetings are taking place with National Agricultural Research Organizations (NAROs) in East Africa that may want to join the initiative. The research partners also call on donor organizations to provide funding and on potato breeding companies to support the initiative "by making know-how and material available."[385] To facilitate this last point, it is emphasized that, "While the focus is the impact on food security for the resource poor, parties aim to ensure at the same time that breeding and seed sales companies will not be adversely affected by this initiative".[386] This reflects the aforementioned issue that companies are hesitant to making technologies available for humanitarian purposes as this may backfire on their commercial interests. It also shows that public research organizations take much care not to harm companies' interests in their broader research activities, including those in the area of international development cooperation.

The main reason for this is that Wageningen UR works closely together with the private sector on various potato research projects. Together with the Ministry of Agriculture, Wageningen UR and several private companies agreed to join all the know-how, research materials (genes) and IPRs developed in the various research programs on potato and late blight in order to stimulate their broad and efficient use and increase the impact of their results. The owners of the resources in question have formed a consortium and signed a

383 Wageningen UR, International Potato Center and Cornell University 2009. Available at <http://www.durph.wur.nl/NR/rdonlyres/FB82D838-39ED-4AB9-8319-691886CA0821/92525/LetterofIntent.pdf> (accessed on March 16, 2011).

384 See *e.g.* the White Paper on cisgenesis, available at <http://www.cisgenesis.com/content/view/4/28/lang,english/> (accessed on March 16, 2011).

385 Wageningen UR, International Potato Center and Cornell University 2009, p. 1.

386 *Idem*, p. 1.

Consortium Exploitation Agreement, in which the way the resources are managed and exchanged is established. These resources are normally exchanged under non-exclusive licenses for which (market-level) royalties are to be paid, but discounts apply depending on the size of contributions made to the consortium. With respect to the DuRPh project, a first concept of a humanitarian use license has been drafted that would apply to all contracts between the consortium members in order to secure the availability of the relevant knowledge, research materials, and IPRs. The consortium may also grant sublicenses to outside organizations for humanitarian use. The concept note will be worked out in detail once the development of marketable products will come into sight.

In the concept note, 'humanitarian use' is defined as "research and development activities (not-for-profit and non-commercial activity) conducted with public and/or charitable support for the public good and to the benefit of sections of the general public in developing countries in need of particular assistance. It is including but not limited to such aims as poverty alleviation and the movement of subsistence farming systems toward a market economy."[387] The relevant developing countries are selected from the World Bank classification lists of low-income and lower-middle-income economies[388] according to their specific needs and targeting the alleviation of hunger and poverty. 'Subsistence users' are more specifically defined as:

"users or consumers of products made from or embodying the relevant IP:
- for direct personal or family consumption
- for barter (exchange) for personal or family food, shelter, fuel or clothing
- in trade or business resulting in monetary income less than €10 000 per year per business entity"[389]

Further provisions hold that a humanitarian use license will be restricted to a country or region, and that such license will explicitly exclude the right to export the harvested potatoes or any type of product derived from it.[390] A final issue is that the late blight resistance genes will not be crossed with/placed in potato varieties that fall under IP protection (patents or PBRs) of third parties, in order to prevent royalties from having to be paid and the humanitarian license having to be negotiated with the owner of the protected variety.

As the movement of subsistence farming systems toward a market economy is also recognized as an important aspect for which materials provided under the humanitarian use license can be used, some of the people involved consider it a risk that the line between farmers that produce for local and national markets and those that also enter the global export market may be difficult to distinguish and control. Yet, does this mean that the humanitarian licensing strategy should indeed be feared and only be accepted in return for a lower licensing fee? Probably not: Albeit it may happen that some farmers or companies will misuse the licensing terms and sell their harvest or derivative products on the international market, competitors will be liable for damages as they do not fall under the above definition of 'subsistence users'. From a moral point of view, such risks do not outweigh the potential benefits of providing the material for humanitarian use, which may well be considered a

387 Draft Humanitarian Use License [not public] 2009.

388 See <http://data.worldbank.org/about/country-classifications> (accessed on March 16, 2011).

389 Draft Humanitarian Use License [not public] 2009.

390 *Idem*.

moral imperative for publicly funded research organizations. Furthermore, as the Dutch seed potato sector is the world's market leader, it will also benefit itself from the development of new markets in these countries.

In case the DuRPh project leads to late blight resistant potato varieties that are successfully marketed and, at the same time, sustainably grown by subsistence farmers in developing countries, the project can be considered a *best practice* of how to connect international development objectives with national knowledge and innovation agendas (see Chapter 5).

### 6.3.4 Brassica Case

In 2002, the public-private Collaboration on Insect Management for Brassicas in Asia and Africa (CIMBAA) was started, on initiative of the Natural Resources Institute (NRI) of the University of Greenwich. NRI invited Nunhems to join the initiative, which is a Dutch subsidiary of Bayer CropScience and one of the world's leading suppliers of vegetable seeds.[391] Next to NRI, the CIMBAA consortium included three other public partners (the World Vegetable Centre AVRDC, Cornell University and the University of Melbourne), plus a number of research partners, including WUR, that addressed specific research aspects of the project.[392] Nunhems financed about 50% of the project, while the other half was mainly funded by donor organizations such as the UK Department for International Development (DFID), the US Agency for International Development (USAID), and the Australian Centre for International Agricultural Research (ACIAR).

The project aimed to develop transgenic cabbage and cauliflower varieties[393] that are resistant to the diamond back moth.[394] This is a major pest in over 80 countries, causing production losses of 30% to 80% in the developing world at a cost of over $1 billion US dollars a year.[395] Losses even take place in insecticide protected crops that are sprayed weekly or even more often, adding significantly to production costs and creating substantial environmental and health hazards.[396] The project focused initially on India, which is the world's largest producer of cauliflower (on 45,000ha) and the second largest producer of cabbage (on 270,000ha), mostly grown by smallholder farmers.[397] Eventually, the project could be expanded to include other Asian and African countries.

The fact that the project concerned a GM technology complicated the start-up phase, mainly because several public funders and research organizations were hesitant to get involved for fear of the damage this could inflict on their public image. In order to ease social anxiety, the consortium took much effort to first investigate socio-economic aspects and to develop a safe and durable technology. It was decided to develop a dual Bt gene construct by using genes from two different Bt proteins (Cry1Ba and Cry1Ca) in order to substantially delay

391 See <http://www.nunhems.com/www/nunhemsinternet.nsf/id/CW_EN_About_Us-_Overview?open> (accessed on March 16, 2011).

392 See <http://www.cimbaa.org> (Not accessible anymore).

393 *Brassica oleracea.*

394 *Plutella xylostella*; the project also aims at resistance to other lepidopterous pests such as cabbage cluster caterpillar (*Crocidolomia pavonana*) and cabbage webworm (*Hellula undalis*).

395 Talekar and Shelton 1993.

396 Sandur 2004.

397 Mohan & Gujar 2003.

the possible evolution of resistance within the targeted insect populations (see Box II-18). Once developed and tested, this technology would then be disseminated "for further breeding and commercialization under strict stewardship guidelines, to interested seed producers in countries in which the material is registered, without restrictive license or other fees."[398]

**Box II-18:** ***Technology Development for Resource-poor Farmers***

*The choice to develop a dual Bt gene construct had much to do with the aim to make the technology fit for use by resource-poor farmers in developing countries.[399] Normally, farmers are obliged to sow 'refuge areas' with non-resistant crops so as to delay the build-up of insect resistance against the Bt toxin. Yet, this can be problematic for resource-poor farmers who need to cultivate their entire holding to make a living, and their compliance with such regulations is difficult to control and enforce. The stacking of two Bt genes would delay the build-up of insect resistance even if no refuge areas are in place. The consortium had also chosen to closely link the two genes on one chromosome in order to secure their joint pairing in any further crosses, as the material would be available for further breeding – outside the control of the technology developers. A final decision was to develop male sterile hybrids instead of open pollinated varieties in order to eliminate the risk for unintended cross-pollination with cultivated and wild Brassicas.*

By the end of 2006, a first series of contained field trials in India was started, resulting in two elite events – one for cabbage and one for cauliflower – demonstrating successful pest resistance in 2008. In spite of these successes, the consortium has recently decided to terminate further development of this material. Before discussing the main reasons for this, we will first describe some arrangements with respect to the ownership and management of IPRs within the consortium.

One important feature is that all IPRs related to the applied technologies and traits – about 20 patents in total – were covered by the patent and license portfolio of Nunhems' mother company, Bayer CropScience. This was considered "practically essential for the project to succeed"[400] as it guaranteed the freedom to operate for both the development and commercialization of the technology. Otherwise, the transaction costs for negotiating such freedom with third parties would likely be too high and time consuming for the project. In this context, it must be mentioned that transaction costs are relatively high for horticultural crops because of the smaller markets (e.g., as compared to field crops) in which R&D investments have to be recovered.[401] Yet, as the return on investment for any humanitarian project will be rather weak, IP-related transaction costs are likely to weigh heavily on the available resources, forming a serious impediment to the execution of such projects.

Another remarkable feature - as announced in various publications and presentations of the CIMBAA project[402] - is that the ownership of the material, including all IPRs and regulatory dossiers, would be transferred to AVRDC – a not-for-profit international research organization

398 Russell *et al.* 2008, p. 272.

399 Vroom 2009.

400 *Idem*, p. 109.

401 Graff *et al.* 2004.

402 See <http://www.cimbaa.org> (Not accessible anymore).

– once the Bt Brassicas had been developed and tested. This public partner would then license the material back to Nunhems and, from the day that Nunhems would enter the market, to any other competent breeder interested to breed the trait into their own varieties. Neither AVRDC nor any of the subsequent licensees would have to pay royalties for the material.[403] This would allow the price of the seed to be kept at a reasonable cost, making it affordable for resource-poor farmers. Furthermore, the non-exclusive license strategy allows for a differentiation in the market, in which each breeding company can choose to cross the Bt material with varieties that suit their own (niche) markets. This can stimulate a wide dissemination of the technology and increase its availability.

So, despite the fact that the Bt Brassicas would fall under various patents, it was decided to make the varieties freely available for further breeding (as is common with plant breeder rights). On the one hand, this decision resulted from the fact that public donors had invested 50% of the project. On the other, we learned from the interviews that the initiative was largely driven by a few individuals within Nunhems, who strongly emphasized 'their' corporate social responsibility. Yet, the company also had something to win. Firstly, Nunhems had the right to be the 'first to market', which in the breeding industry is a considerable advantage. Secondly, because Nunhems already had a market position in India, the company would have had a competitive advantage with its elite germplasm and advanced production system, producing high quality hybrids for the market's top segment. And thirdly, the new Bt technology was considered "instrumental in allowing for the continued cultivation of Brassica in India",[404] and, thus, for maintaining and possibly enlarging the market for the company's products.

Despite the well thought out organization of the research program and the first successful field trials, the program stopped late 2010. The main cause for this discontinuation relates to *liability*. According to the Cartagena Protocol on Biosafety, a technology developer can be held liable for financial claims in case of damage caused by GM technology. Bayer CropScience has been facing major lawsuits in the US as an unapproved GM rice variety developed by that company was found in the food chain in August 2006 after it had been tested by a US university.[405] This has not only scared Nunhems' mother company but also CIMBAA's public research partners, which "would not take 'ownership' and with that 'liability'".[406] Other reasons mentioned are the stewardship requirements being "too onerous to allow for germplasm sharing", and, again, the GM regulatory hurdles that "make time-lines and costs very uncertain."[407] Momentarily, discussions are continuing about some of the plant and genetic material to pass into public hands, for example the Indian Council for Agricultural Research and/or the CGIAR.[408]

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403 Yet, there was a plan to collect some revenues from the sublicensing in order to fund stewardship activities such as the training of farmers and resistance monitoring (Russell *et al.* 2008).

404 Vroom 2009, p. 105.

405 Reuters 2010.

406 Kaliaperumal *et al.* 2011.

407 *Idem*.

408 *Idem*.

### 6.3.5 Conclusion

The four case studies give a good picture of the major issues that can come to the fore when developing a technology that falls under IP protection (in-house or third-party IP) for use by resource-poor farmers in developing countries. Central issues relate to one's freedom to operate, the use of humanitarian licenses, and the costs and risks concerning GM technologies. These topics, and the conclusions that can be drawn from the above cases studies, will be discussed in detail in the next section.

## 6.4 How do IPRs Affect Pro-poor Innovation: Problems, Opportunities, and Non-IP issues?

So what can we now say about the effects IPRs have on pro-poor innovation, i.e., the development and transfer of knowledge and technologies for the benefit of resource-poor farmers in developing countries? In this section, we discuss the major findings from our research in the Netherlands, and assess the *problems* and *opportunities* that IPRs can create, but also reflect on the relative importance of IPRs vis-à-vis *non-IP issues*.

### 6.4.1 Problems

1. *Freedom to operate and other costs.*

When assessing the impact of IPRs on accessing and transferring research materials as experienced by the Dutch interviewees, we have to distinguish between different types of research. The public researchers indicated that for research purposes most research knowledge, technologies and materials are still freely exchanged, even when patented technologies are concerned. However, the Material Transfer Agreements (MTAs) that are currently applied do not allow for product development or any commercial application of the material. This can create problems for pro-poor innovation projects, as these often involve applied research trajectories that, for example, aim at the development of improved seeds for resource-poor farmers. This goes beyond the standard permissions in MTAs and does not fall under the research exemption of the Dutch Patent Act. It implies that for such projects, additional access and use conditions have to be negotiated with the technology owners, which will increase transaction costs.

Such costs do not merely relate to the payment of license fees and royalties but to all the costs involved in assessing and accessing third party IP, i.e., all the time and expertise needed to investigate one's freedom to operate and to negotiate the necessary licenses. The shallot and Brassica cases especially exemplified the importance of having access to a strong IP portfolio to secure freedom to operate both for the development, implementation and commercialization of a technology. Yet, most humanitarian projects will not be able to establish such position and, as the return on investment for any humanitarian project will be small, IP transaction costs can form a serious impediment to such projects. The shallot case showed that patent owners may simply not reply to questions concerning the conditions for using their technology, which creates legal uncertainty for the technology users.

The broader discussion on freedom to operate in the agricultural research sector appeared to be dominated by the patent vs. Plant Breeder's Rights debate. But what is the relevance of this debate for developing countries? According to the pro-PBRs camp, the

current problems with the patent system are likely to impact heavily on developing countries, especially in the long term. Hereby, the increasing consolidation in the plant breeding sector is regarded to be most problematic for several reasons. First, genetic diversity might decline – with all consequences for global food security – when only one or two companies control the global seed market for a specific crop. Second, prices may rise due to the lack of competition. Third, a very small number of breeders will lead to ever more standardization in breeding and seed production, leaving aside the specific needs of developing country markets and climate zones.

More generally, the most referred-to obstacles that patents may create for developing countries and pro-poor innovation have to do with the costs involved. First, there is the high cost of drafting, filing and maintaining a patent (see Box II-15). Second, assessing, accessing and transferring patented technologies involve major transaction costs, as explained above. And third, the costs of litigation if one is accused of patent infringement, or if one has to oppose or defend a patent at the patent office or in court, are likely to be far higher. The fact that Dutch universities and even multinational companies report to have difficulties with bearing these costs leaves many questions for the position of research organizations in developing countries or pro-poor research initiatives.

The pro-PBRs camp emphasizes that PBRs are "very much cheaper" than patents.[409] First, the application and maintenance costs are lower. More importantly, the transaction costs are much lower because no royalties have to be paid when using protected varieties in breeding programs, and, consequently, no freedom to operate studies and negotiations have to take place. And third, the breeders' exemption also implies that PBRs are hardly ever challenged in court, saving all costs involved. Obviously, the pro-patent camp opposes these arguments by stating, in essence, that the weakening of patent protection through a breeder's exemption will threaten innovation in the sector by undermining the possibilities to recoup the necessary investments. Developing countries should keep a close eye on this debate in order to carefully balance the pros and cons of the different IP systems when implementing their own IP policies.

2. *Little use of humanitarian licensing strategies*

Where transaction costs come to the fore when using third party IP, one can decide under what conditions in-house IP can be accessed by others. Hence, public research organizations can make sure that their intellectual assets are available for humanitarian use in developing countries, even when patented and/or licensed to third parties. This is, for example, done by several public research institutions in the US (see Box II-18). In the Netherlands, however, we only came across one research group applying humanitarian use licenses in some of its research and IP contracts, and none of the examined universities have incorporated a reference to humanitarian licensing in their official IP policies.

[409] Plantum NL 2009, p. 6.

**Box II-19: *Universities for Humanitarian Use***

*In 2007, twelve universities in the US presented the white paper In the Public Interest: Nine points to consider in licensing university technology.*[410] *In this paper they pledge to "Consider including provisions that address unmet needs, such as those of neglected patient populations or geographic areas, giving particular attention to improved therapeutics, diagnostics, and agricultural technologies for the developing world."*[411] *The paper discusses various IP management tools to realise this objective, and it has an appendix listing several examples of contract clauses and licensing terms. One of the US universities that has put this into practice is the University of California, Berkeley. They developed a Socially Responsible Licensing Program, which involves various licensing mechanisms that aim to maximize the impact of their research by ensuring widespread availability of research materials, technologies and end-products for and in the developing world.*[412]

There are different reasons for this lack of humanitarian licensing in the Netherlands. One of them is that valorisation of research, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is currently the primary driver for IP policymaking at all layers of the public research system. As discussed in the previous chapter, international development considerations do not feature in this discourse. Furthermore, there is little knowledge of humanitarian licensing strategies at the level of government and funding agencies, and they have no policies in this area. IP holders and managers at public research organizations therefore have no incentives to include humanitarian use clauses in their contracts with third parties.

Another important factor is that public research organizations are strongly focused on the private sector in order to generate alternative income streams by means of research contracts and partnerships. This is also strongly stimulated by the Dutch government.[416] This has consequences for the application of humanitarian use clauses, as it depends on the willingness and acceptance of all parties involved whether these are included in research contracts or IP licenses. The importance of the private sector for universities is also illustrated by the humanitarian licenses discussed above (i.e., the cassava and potato case). The text of these clauses are carefully phrased in order to make sure that the private partners' interests are not adversely affected, by explicitly excluding the right to export (derivatives from) the material provided for humanitarian use.

It was indeed reported that many companies do not favor the use of such licenses because of the risk that a protected technology, which is provided royalty free for

410 California Institute of Technology *et al.* 2007. Available at <http://www.fptt-pftt.gc.ca/eng/news/2007/docs/mar07_white_paper.pdf> (accessed on March 16, 2011).

411 *Idem*, point 9, p. 8.

412 Mohiuddin and Imtiazuddin 2007. Available at <http://www.acumenfund.org/ uploads/assets/ documents/ Acumen%20Fund%20-%20Socially%20Responsible%20Licensing%20-%20July%202008_kYAIb8kF.pdf> (accessed on March 16, 2011).

416 See Chapter 5.

humanitarian use, ends up in a competitive product on the market. Consequently, public research organizations are reluctant to make humanitarian licensing a standard policy because they fear that this would lead to less contracts and partnerships with companies or lower licensing fees. Specialists in the area of humanitarian licensing emphasize, however, that "Licensing IP for applications to benefit the poor can be achieved without compromising core commercial markets of the IP owners."[417] By using the right legal tools for a specific technology and project partnership, humanitarian licenses can mitigate risks and lower transaction costs.[418] There are several international organizations and initiatives to which Dutch universities can turn to in order to learn more about, and even to get advice on how best to reconcile their financial interests with their social responsibility to ensure that the research findings are available for those who need them most (see Box II-19).

The fear that companies are scared away by the inclusion of humanitarian licenses may well be unfounded. Public research organizations should not underestimate their negotiation position vis-à-vis the private sector, even if they would make humanitarian licensing a standard policy. They possess a wealth of knowledge and expertise that is of interest to companies, and most public-private partnerships are still financed for the majority with public money. Yet, relations of trust and proper IP management are important preconditions for companies to be confident about the inclusion of humanitarian licenses in their contracts with whatever research partner. So, in order to stimulate the use of such licenses, the public sector would benefit from developing clear and transparent policies, both at the level of ministries and funding agencies and at the level of individual research organizations, together with building more legal expertise and capacity on humanitarian licensing strategies, IP stewardship, and negotiation skills.

**Box II-20:** ***International Knowledge Resources on Humanitarian Licensing***

*The Public Intellectual Property Resource for Agriculture (PIPRA) initiative initially aimed to serve as a clearinghouse by bringing together patent information from major public research organizations, and helping these institutions with applying humanitarian use licenses, in order to reduce transaction costs and stimulate technology transfer to the developing world.[419] Now, PIPRA provides a range of IP and commercialisation strategy services that, supported by a pro-bono attorney network, help public research organizations to get their innovations to those who need them most. They have also published an elaborate IP handbook of best practices[420] on which website a long list of all sorts of sample agreements can be found.[421]*

*The initial PIPRA objective is now taken up by a new and promising initiative that is called Global Access in Action.[422] This initiative aims to assist owners of intellectual assets to "strike the right balance between preserving commercial markets and creating access to technology for the poor." The initiative will work through four major implementing partners: the World Intellectual Property Organization (WIPO), Global Access to Technology for Development (GATD), PIPRA, and the*

417 See <http://globalaccessinaction.org/> (accessed on March 16, 2011).

418 *Idem*.

419 See <http://www.pipra.org/about/> (accessed on March 16, 2011); Atkinson *et al.* 2003. <http://www.sciencemag.org/content/301/5630/174.summary?ijkey=bJhyNVg9ELVzc&keytype=ref&siteid=sci>

420 Krattiger *et al.* 2007. Available at <www.ipHandbook.org> (accessed on March 16, 2011).

421 See <http://www.iphandbook.org/handbook/resources/Agreements/> (accessed on March 16, 2011).

422 See <http://globalaccessinaction.org/> (accessed on March 16, 2011).

*Licensing Executive Society (LESI). Together, they aim to provide "legal tools to cut licensing and partnership transaction costs, connecting partners to demand driven innovation opportunities, and integrating commercial strategy into technology transfer for development."*[423] *For this purpose, a patent information clearinghouse and IP licensing and partnership agreement toolkit are being developed, amongst others.*

*Another resource for information on humanitarian licensing, and some examples of its implementation in agriculture (e.g., Golden Rice Consortium; Generation Challenge Program), can be found on the website of the Central Advisory Service on Intellectual Property (CAS-IP) of the CGIAR.*[424]

### 6.4.2 Non-IP issues

1. *Broader challenges*

Several interviewees warn that the (negative) impact of patents or other IPRs on the development and transfer of knowledge, technologies and materials for the benefit of resource-poor farmers in developing countries, should not be overestimated. One of the central arguments is that most protected technologies go beyond the absorptive capacity of developing countries, and that there is much non-patented technology and knowledge available that is more relevant for developing countries at this moment. The respondents indicate that basic investments in local breeding programs and the implementation of some agronomic improvements at the farmer fields would already have major impacts on yields and product quality, especially in Africa. Overall, the lack of good infrastructure, educational system, and governance structures, next to deficient financial resources for research and development, are generally considered more important impediments to improved agricultural output than issues of IP. Looking purely at agricultural research and development, the lack of technological capacity in many developing countries, both in terms of facilities and the number of trained breeders and researchers, is considered the number one problem. This problem also limits the uptake of relevant non-patented technologies in developing countries.

Obviously, these broader challenges need to be addressed if a strong agricultural sector is to be realized in developing countries. IP protection is, however, an important factor in that development process, influencing both national and international technology and capital flows and power balances, and is therefore not to be ignored.

2. *Genetic modification*

The most influential non-IP issue affecting technology transfer to developing countries relates to the use of genetic modification (GM) technologies. Actually, this is the decisive factor

[423] *Idem*.

[424] See <http://www.cas-ip.org/ip-agriculture/equitable-access-licences/> (accessed on March 16, 2011).

[431] COGEM 2008; Kalaitzandonakes, Alston and Bradford 2007.

behind the failure of three of the four case studies discussed above, and it plays a major role in the future success of the potato case. There are several key problems to be discerned.

First, there is the *cost issue*. Apart from the fact that most GM projects involve substantial research costs, it is especially the costs of getting a GM crop through the biosafety procedures that count. One interviewee estimated these regulatory costs between six to ten million euros per crop.[431] As was exemplified by the shallot case, such costs are well out of reach for most if not all universities and even for many companies, particularly when applied to so-called 'orphan crops' and for resource-poor farmers in developing countries. But also for cash crops such as soybean, the costly and time-consuming regulatory process can create a new form of exclusivity that goes beyond patent protection. This is exemplified by the current debate on the first GM crop coming off patent in 2014 (see Box II-20).[432]

**Box II-21 : *Biosafety Dossiers Can Block Generic Competition in Agro Biotechnology***

*In the coming years, many GM technologies and traits will come off patent, and Monsanto's herbicide-tolerant Roundup Ready trait in soybean is the first in 2014. This is the first time that generic versions can be developed in agricultural biotechnology and, in contrast to the pharmaceutical industry, no specific legislation or sector protocol is yet in place to pave the way from patent monopoly to generic competition. This lack of transparency is worrying since a GM crop needs to go through extensive biosafety tests before it is allowed to be marketed in a particular country. The biosafety dossier that results from this regulatory process is confidential and the owner needs to maintain it over time. The technology developer can, therefore, decide to terminate the regulatory dossier by the time its patent on the technology expires. This would imply that no one can develop a generic version without going through the same costly and time-consuming regulatory process. In the case of Roundup Ready soybean, Monsanto has pledged to maintain export approval status through 2021.[433] Eventually, however, the sector or governments will have to develop a mechanism to maintain the biosafety dossiers long term, for example by making them publicly available.*

A second problem is the *social controversy* that surrounds the technology and its products. The Brassica and shallot cases showed that public funders and research partners can be very reserved when it comes to supporting a project in which GM technologies are used. Furthermore, governments can easily decide to delay or deny the regulatory approvals for such projects. To counter both the cost and social controversy issue, researchers involved in the potato case take much effort to explain that cisgenesis should not be considered a GM technology as it only works with natural genes, i.e., genes from the same species or its crossable wild relatives.[435]

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432 Parloff 2010.

433 Abbott 2011. Available at <http://greenbio.checkbiotech.org/news/gm_crop_patents_near_end_us_farmers_ask_what_next> (accessed on March 16, 2011).

435 See *e.g.* the White Paper on cisgenesis, available at <http://www.cisgenesis.com/content/ view/4/28/ lang,english/> (accessed on March 16, 2011).

A third major issue relates to *liability*. According to the Cartagena Protocol on Biosafety, a technology developer (often the patent holder) can be held liable for financial claims in case of damage caused by the GM technology. Together with the social controversy surrounding the technology, companies and research organizations are generally very concerned about whom to share their technologies with and under what conditions, as they fear brand damage and liability claims in case of misuse or bad product performance. This has particularly been exemplified by the CIMBAA case, where liability risks discouraged both the private and public partners to continue the research project.

Furthermore, many governments have set up strict regulations on the growing of GM crops in order to allow for the coexistence with conventional and organic crops.[436] A GM variety is therefore released on the market with tight stewardship conditions attached. These circumstances can have different effects on IP management and technology transfer to developing countries. On the one hand, it is repeatedly indicated that the risks involved make patent holders hesitant to grant humanitarian use licenses, as this may weaken their control over the technology.[437] Also, breeders may focus even less on resource-poor farmers as these will be unable to adopt the necessary stewardship measures, resulting in liability issues. On the other hand, in relation to the potato case there are some voices that would like to investigate how IPRs, as a control tool, can contribute to the sustainable management of the late blight resistance genes in the field.[438]

### 6.4.3 Opportunities

1. *Patent databases*

With respect to accessing outside knowledge and technologies, several non-IP problems were mentioned. Central is the difficulty of getting to know 'who is doing what' and finding out what technologies are already available. The expensive subscription fees for many scientific journals are certainly problematic in this context. Patented technologies are, however, relatively easy to trace as they are registered in various patent databases, many of which can be freely accessed. Furthermore, the patent system demands the publication of each invention so that a person 'skilled in the art' can reproduce it. Patent databases contain thus a valuable source of information and, since currently many biotechnologies are not patented in developing countries, such databases could provide the researchers in these countries a manual for copying the patented inventions.

Yet, different opinions exist whether the information included in these databases is indeed sufficient for repeating the patented inventions, with some arguing that essential information is often deliberately omitted. Even though there is no doubt that some inventions can be copied by means of the disclosed information, the importance of *know-how* was also strongly emphasized, especially in biotechnology. Know-how generally refers to all information, materials, and technologies needed that are not publicly available. This includes all the facilities (labs, greenhouses, genebanks, etc.) that an inventor has access to and which can be indispensable to repeat the patented invention. Still, it must be emphasized that it can

436 See *e.g.* <http://ec.europa.eu/agriculture/gmo/coexistence/index_en.htm> (accessed on March 16, 2011).

437 Heselmans *et al.* 2008. Available at <http://www.society-genomics.nl/uploads/media/IP-Policies-Conference-11april2008-Report.pdf>(accessed on March 16, 2011).

438 Haverkort 2009. Available at <http://www.durph.wur.nl/NR/rdonlyres/A03C74F6-7B5E-42A0-85B0-3919AD0BB3BE/82122/PotatoWorldaboutDuRPh.pdf> (accessed on March 16, 2011).

be more difficult to get access to an unpatented invention because of the simple fact that it was not disclosed to the world.

2. *Need for an effective protection system*

Several interviewees argued that developing countries would benefit from establishing a proper PBRs system as this would make it possible to have more control over the development, quality and dissemination of new seed materials. With respect to the patent system, the incentive that such system can create for innovators and investors was repeatedly mentioned as an important opportunity for developing countries. Other opportunities that IPRs can present to developing counties, according to the Dutch interviewees, relate to their effect on foreign partnerships and investments. Important in this respect is the observation that many research organizations and companies from the developed world only want to collaborate with partners in developing countries when they can be sure that their technologies are properly protected and managed. Along that same line, most industry representatives indicated that they will only invest in developing country markets if they can protect their products from being copied, either by legal (i.e., IPRs) or technical means (i.e., hybrid seeds[439]). Another argument why developing countries should establish an efficient IPR system according to some interviewees is that "you have to play by the rules if you want to be part of the game," meaning that if a developing country wants to enter an export market it has to comply with the international IP regulations and IPRs.

## 6.5 Conclusions

In this chapter, we have analysed the effects IPRs have on the accessibility of research materials and the transfer of agricultural technologies to developing countries, by discussing the experiences of actors in the public and private sector and four case studies. This was followed by an evaluation of the positive and negative roles of IPRs vis-à-vis non-IP factors.

The public researchers interviewed indicate that most research materials (also when protected by IPRs) are still freely exchanged without serious delays. However, some companies were reported to set very restrictive conditions, claiming that all future inventions made on or with the material provided will fall under their IP. Together with the weak research exemption in patent laws in many countries, this can thwart public research on commercially developed technologies as in the case of GM crops. Universities make sure to protect their own freedom to operate with respect to the IP that results from research for or with private partners. To do so, some try to retain the IPRs that result from research partnerships and only issue licenses to the partners involved. Others indicated, however, that such strategy is too costly in the long run due to the high costs of maintaining a patent. Ultimately, the outcome of 'who gets what rights' in research partnerships depends heavily on the relative contributions of the different research partners and on their negotiation capabilities. All these issues affect the conditions under which university IPRs can be

439 To profit maximally from technical protection measures, the company involved will try to keep the production process secret –*e.g.* when producing hybrid seeds the parent varieties will be kept secret. Another technological protection measure is genetic use restriction technology (GURT), or 'terminator technology', which causes second generation seeds to be sterile. Currently, there is a de facto moratorium on this technology at the United Nations Convention on Biological Diversity (CBD). See *e.g.* <http://www.cbd.int/agro/gurts.shtml> (accessed on March 16, 2011).

accessed, with only 100% publicly funded research is available under non-exclusive licenses and the involvement of private research partners commonly leading to more exclusive arrangements.

Turning to the private sector, the debate on the accessibility of research technologies and materials concentrates strongly on the balance between patents and the 'open source character' of Plant Breeder'sRrights. Proponents and opponents of the current patent system have tabled different proposals, ranging from sector agreements about a restrictive breeder's exemption to the introduction of a full breeder's exemption in international patent law. Other issues under discussion concern the need to increase patent quality or to curtail strategic use of the patent system. Especially the multinational seed companies that are also producing agrochemicals or pharmaceuticals emphasize the importance of strong patent protection for stimulating innovation. Most medium sized and smaller companies however, claim that patents pertaining to plant varieties hamper practical breeding. This is likely to support further consolidation in the seed sector that might lead to higher seed prices and less genetic diversity, with consequences for global food security and particularly the needs of developing countries and poorer farmers.

The four case studies on shallot, cassava, potato and brassica illustrate that IPRs are not the only, nor necessarily the most important, stumbling block to technology transfer in research for development, especially when GM technologies are concerned. Biosafety regulations and the legal and financial risks (e.g., liability) that can come with them can create significant barriers. Furthermore, the public controversy surrounding GMOs can strongly affect the extent to which funders, research partners and, ultimately, farmers and consumers are willing to support the project. It is difficult to separate these issues and assign shares in terms of their importance in technology transfer, also because biotechnology is especially the field in which IP issues play an important role.

The case studies demonstrate the crucial importance of having freedom to operate for the development, implementation and commercialization of a technology. The problems described in the shallot case illustrate the legal uncertainties that can be encountered because of third-party IP. The potato and brassica cases show two strategies (being part of a consortium or having access to a strong IP portfolio) to strengthen or secure one's freedom to operate. Yet, it is very likely that many humanitarian projects will not be able to establish such position and, as the return on investment for any humanitarian project will be small, IP transaction costs can form a serious impediment to such projects.

The idea that humanitarian licenses can negatively affect one's own interests appears to be dominant in the Dutch agricultural research sector. It was reported that many companies have reservations with respect to the application of such licenses because of the risk that a protected technology, which is provided royalty free for humanitarian use, ends up in a competitive product on the market. Consequently, public research organizations are reluctant to make humanitarian licensing a standard policy because they fear that this will lead to less contracts and partnerships with companies or lower licensing fees. Carefully formulated licenses and good IP stewardship can, however, mitigate commercial risks for companies, so the public sector would better start building more expertise in this area, without underestimating their negotiating position or neglecting their public responsibility.

The information provided by patent databases and the importance of an effective protection system for stimulating foreign partnerships and investments, were mentioned as the main opportunities that IPRs can present developing counties.

# CHAPTER 7 CONCLUSIONS

## 7.1 Introduction

This final Chapter sums up our main conclusions along the following lines. The first two sections assess the role of IPRs in the management and sharing of knowledge related to seeds and varieties for development (the achievement of MDG 1c) by summarising our conclusions on 1) the main *obstacles* that IP policies and practices can create the development and transfer of such knowledge and technologies for the benefit of resource-poor farmers in developing countries, and 2) the positive roles and *best* IP *practices* that we encountered in this respect. In the last two sections we will reflect on the way forward by listing our recommendations on 3) how this relationship between IP and development (the achievement of MDG 1c) can be improved, and 4) the valorisation and follow-up of this research project.

## 7.2 Obstacles

Hereunder we list those aspects of the various IP policies and practices we encountered that (can) create obstacles for the development, transfer and accessibility of knowledge and technologies for the benefit of smallholder farmers in developing countries. The findings are divided with respect to their relevance for the situation in Uganda / Africa and the Netherlands, followed by more generic conclusions.

### 7.2.1 Uganda / Africa

1. *IPR systems that make informal seed exchange illegal will obstruct the transfer of good seed and improved varieties to resource-poor farmers.* Seeds and new varieties for most crops are accessed by resource-poor farmers solely through informal channels. Only for crops like maize and vegetable seeds is a significant formal sector operational to sell seed to farmers. Some IPR systems make reuse of seed illegal (patents), others do not allow the exchange and sale of farm-saved seed (breeder's rights according to UPOV). Implementation of such rights will obstruct access to better varieties by resource-poor farmers. (Chapter 1 and 2). However, this means that public funds need to be invested in research and breeding for such target groups.

2. *IP may have profound impact on the public agricultural research system.* There is clear evidence that the IP policy landscape in Africa's agricultural research institutions and universities is changing. The growing perception that IP protection may provide a funding lifeline for agricultural R&D has the potential to tilt the focus of these institutions towards more commercially viable crops and farmers, and away from poverty reduction goals. It is clear that the majority of the rural populations in Uganda and elsewhere in Africa depends on a wide range of crops to mitigate the risks of hunger. Institutional IP policies have not yet properly aligned with public research mandates. This makes IP more of an obstacle than an instrument to shape agriculture R&D towards the technology needs of smallholder farmers. (Chapter 4)

3. *Low awareness of IPRs with research directors and limited capacity for IPR management create poorly framed institutional policies, and creates obstacles for international research cooperation and effective technology transfer.* Lack of knowledge of IPRs create a research environment that either obstruct collaboration with northern partners (public or private) or provide opportunities for more knowledgeable partners to take advantage of the less aware. We show that research collaboration contracts are not always sufficiently to the benefit of the developing country partner. (Chapter 3 and 4)

4. *Uganda lacks the necessary institutional architecture to harness the benefits of IP.* In order to harness the benefits of IP protected knowledge and technology, countries need robust institutions organized in the form of a national system of innovation and each of them capacitated to play their different roles. IP policy institutions must be able to work alongside agriculture R&D institutions, technology development and dissemination institutions, IP regulatory agencies and many others within such an integrated system. Ugandan institutions exercising IP-related mandates are quite disjointed or only coordinate with each other in an ad hoc manner. In this regard, IP is unlikely to be applied in a manner that offers tangible benefits to Uganda or smallholder farmers. (Chapter 3)

5. *International top-down push for IP policy undermines the potential role of IP at the national level.* The formulation of IP policy at the national and international level in most African countries is driven by the international agenda based on the WTO TRIPS Agreement, bilateral and regional trade agreements and the policies of international agricultural research and funding agencies. This makes it impossible for developing countries to balance the rights of inventors with those of their society. Capacity development programs (e.g., WIPO and bilateral donors) and rigidity of UPOV in communication with least developed countries furthermore strengthen the vision in local institutions that the rules that operate in OECD countries are optimal. (Chapter 3)

6. *Limited human resource capacity undermines Uganda's ability to take advantage of IP.* Even in the absence of specific policies on IP, existing IP legislation and international agreements contain a series of flexibilities and exemptions that can be better exploited to ensure the use of IP as development policy instrument to address the technology needs of resource-poor farmers. However, Uganda lacks critical human resource necessary to harness these flexibilities and exemptions for the benefit of Ugandan resource-poor farmers. (Chapter 3 and 4)

### 7.2.2 The Netherlands

7. *Dutch IP law lacks a specific development clause and only includes impractical conditions on compulsory licenses.* Despite several international agreements that emphasize the responsibility of the industrialized counties to promote technology transfer to least-developed nations, including TRIPS Article 66.2, no such reference can be found in Dutch IP law. The conditions included in Article 57 of the Dutch Patent Act on compulsory licensing make effective use of this instrument very difficult, which has led to very few applications and no grants in the period 1995-2005. (Chapter 5)

8. *Development considerations are lacking in the IP policies of almost all actors in the public agricultural research system in the Netherlands.* The IP policies of the ministries, funding agencies, national research programs, and public research organizations studied in the context of this research, all lack specific references to international development. This is due to several reasons:

   i. *Valorisation of research, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is the primary driver for IP policymaking in the public research sector*. The concept of valorisation is central to debates on research, innovation and entrepreneurship in the Netherlands, and must be positioned against the background of the so-called knowledge paradox: i.e the perception that the Netherlands is a leader in scientific research but that most knowledge generated does not get translated into innovative and commercial products. IP protection is considered an important tool to facilitate such translation and, thus, to strengthen the Dutch innovation capacity. (Chapter 5)
   ii. *There is no general IP policy at the ministries that finance agricultural research, and opinions diverge on the need of such a policy*. The Dutch ministries do not have a coherent IP policy with respect to the research they finance. The Directorate-General of International Cooperation (DGIS) is the only department that emphasizes the need of such a policy in order to secure the availability of IP-protected technologies for humanitarian use. The need for such policy is not recognized at other ministries and the Ministry of Education, Culture and Science (OCW), which is responsible for the bulk of the research funding, strongly opposes a central IP policy under the guise of protecting the sector's autonomy. (Chapter 5)
   iii. *Awareness among policymakers is low with respect to possibilities for IP to impede access to technologies in developing countries.* Arguments are that such countries do not have an operational IP system in place or that Dutch IPRs are not filed there, and in case access problems do occur compulsory licenses are generally regarded a sufficient solution. Yet, this is not the actual situation: Most developing countries are a long way in implementing TRIPs or TRIPs+ agreements; they have to comply with the relevant IPRs when exporting products; and compulsory licensing has not yet proven to be an effective instrument for developing countries. Furthermore, getting access to IP-protected materials and technologies often involve the signing of Material Transfer Agreements that oblige the user to respect the IPRs involved. (Chapters 3, 4 & 5)
   iv. *International development policy and knowledge and innovation policy are organizationally divided and generally perceived as two worlds apart*. Research and innovation agendas often have a strong national focus, while international development projects are targeted by a few specific departments and funding programs. Consequently, development issues are generally perceived as a world apart from day-to-day business, for which no assignment or resources are available. (Chapter 5)

9. *The involvement of the private sector in public research affects the conditions under which university IP can be accessed, and commonly leads to more exclusive arrangements.* Public

research organizations are strongly focused on the private sector in order to generate alternative income streams by means of research contracts and partnerships, a strategy that is strongly supported by the Dutch research funding system. The conditions for access to IPRs resulting from public-private partnerships are negotiated among the research partners. Commonly, a company contributing to a research project gets at least a right of first refusal to obtain a (non-)exclusive license for the technology in question, or an advantage of some years during which information and materials will be withheld from others. (Chapter 5 & 6)

10. *Dutch public research organizations make very little use of humanitarian licensing strategies in their research and IP contracts with third parties.* Humanitarian licenses protect the possibility for inventors and technology suppliers to share their IP for humanitarian use while maintaining the incentive function of exclusive rights for commercialization with other parties. Even though there are many examples of humanitarian licensing in agricultural research by both public and private organizations from abroad, in the Netherlands we only came across one research group that applied such licenses in some of their contracts with third parties. This is due to several reasons:

    i. *There is very little knowledge of humanitarian licensing strategies in the Netherlands and there are no incentives for its implementation.* Few policymakers, researchers and even IP managers know much about humanitarian licensing strategies, and initiatives such as PIPRA or the Global Access in Action are generally unknown in the Netherlands. Since government and funding agencies have no policies in this area, there are no incentives or resources for IP holders and managers to include such morally just humanitarian use clauses in their contracts with third parties. (Chapters 5 & 6)
    ii. *The idea that humanitarian licenses can negatively affect one's own interests is widespread*. Many companies have reservations with respect to the application of humanitarian licenses because of the risk that a protected technology, which is provided royalty free for humanitarian purposes to a specific user group or region, ends up in a competitive product on the market. Public research organizations fear that a demand for the inclusion of such licenses may reduce their negotiation position with regard to license fees or research contracts. (Chapter 6)

### 7.2.3 General

11. *It is difficult to secure freedom to operate for humanitarian projects given the IP landscape in agricultural biotechnology*. Due to the high number of patents in biotechnology, any research project in this field will probably need to legally arrange access to knowledge, research materials and technologies that fall under third-party IP. This can cause problems for humanitarian projects because of several reasons:[440]
    i. *Material Transfer Agreements (MTAs) often do not allow for product development*. Whereas many research materials are still freely exchanged, even when protected by

[440] There are several other IP related issues that impede freedom to operate in agricultural biotechnology, irrespective of whether a humanitarian project is concerned. These are discussed separately below.

IPRs, the accompanying MTAs normally allow use for research purposes only. Humanitarian projects that involve applied research trajectories to develop, for example improved seeds for resource-poor farmers, go beyond the standard permissions in MTAs and do not fall under the research exemption in patent law. (Chapter 6)

ii. *High transaction costs*. Transaction costs relate to all costs involved in assessing and accessing third party IP, i.e. all the time and expertise needed to investigate one's freedom to operate and to negotiate the necessary licenses, next to the eventual payment of license fees and royalties. Having a strong IP portfolio is therefore of crucial importance. Yet, many humanitarian projects will not be able to establish such position and, as the return on investment for any humanitarian project will be small, IP transaction costs can form a serious impediment to such projects. (Chapter 6)

12. *Restrictive licensing conditions by some companies, and the weak research exemption in most patent laws, can in practice block the availability of protected technologies for scientific research*. Some biotechnology companies apply very restrictive conditions in their MTAs, claiming for example that all future inventions made on or with the material provided will fall under their IP. Also, the research exemption in many countries does not give public researchers much leeway. To do research on heavily protected technologies like GM crops, scientists have to ask permission to the technology owner, meaning that no independent research can be conducted. (Chapters 5 & 6)

13. *Some aspects of the current patent system lead to unbalanced market conditions in favor of the largest companies*, *which may have negative consequences for developing countries*. It is feared that the current patent system stimulates further consolidation in the seed sector, which might lead to higher seed prices and less genetic diversity, with all consequences for global food security and particularly the needs of developing countries and poorer farmers. The consolidation is fuelled through IPR by several aspects:

i. *The high costs involved in patent maintenance, transaction and litigation*. First, there are the high cost of drafting, filing and maintaining a patent. Second, assessing, accessing and transferring patented technologies involve major transaction costs. And third, the costs of litigationare likely to be far higher when one is accused of patent infringement, or when one has to oppose or defend a patent at the patent office or in court,. The fact that Dutch universities and even multinational companies report to have difficulties with bearing these costs leaves many questions for the position of research organizations in developing countries or pro-poor research initiatives. (Chapter 6)

ii. *Strategic patenting*. Strategic patenting is the deployment of the patent system to primarily serve strategic objectives rather than commercializing the very invention that is protected. In the extreme case, it is applying for patents with the only objective to block competitors in the market or in a research area. Those with the deepest pockets and biggest IP portfolios have most possibilities to deploy (or defend themselves against) strategic patenting. (Chapter 6)

*iii. Patents extending to plant varieties hamper the accessibility of these varieties for further breeding as most patent laws do not include a breeder's exemption*. Commercial breeders unable to obtain licenses for all the traits they need likely lose their competitive position in the market, which leads to more consolidation in the sector. And as breeding has and will always depend on crossbreeding in order to fight biotic and abiotic stresses, impediments to the availability of genetic material for further breeding may also hamper global food security. (Chapter 6)

14. *The difficulty of finding out which technologies are available and getting to know 'who is doing what' can create obstacles for resource-poor researchers in developing countries*. This problem is intensified by the expensive subscription fees for many scientific journals. Patent databases, on the other hand, form a valuable source of information. Yet, opinions diverge as to whether the information disclosed is always sufficient for repeating the described inventions, especially because of a lack of access to the necessary know-how, i.e., all the materials, knowledge, and research facilities that are not publicly available. (Chapter 6)

15. *The regulatory obligations and social controversy surrounding GM technologies, together with the liability risks involved, can form a major impediment to the successful application of such technologies in development projects*. The costs of getting a GM crop through the biosafety procedures are significant. Moreover, the technology developer (often the patent holder) might be held liable for financial claims in case of incidents or damage caused by the GM technology. This means that companies and research organizations are generally very concerned about whom to share their technologies with and under what conditions, as they fear brand damage and liability claims in case of misuse or bad product stewardship (Chapter 6)

16. *The termination of GMO market registration can block generic competition in agricultural biotechnology*. The biosafety dossiers that permit the production and/or marketing of a GM products in a particular country are held confidential. The technology developer can, therefore, decide to terminate the regulatory licenses by the time its patent on the technology expires. This implies that no one can use a generic version without going through the same costly and time-consuming regulatory process. (Chapter 6)

## 7.3 Best Practices

In spite of the obstacles outlined above, this study also points to some policies and practices that are likely to ensure a positive role of IP in facilitating the development, transfer and access to agricultural innovations for resource-poor farmers. Furthermore, some of the obstacles described above are countered by the development of different IP and non-IP solutions. Below we summarize our major findings with respect to their relevance for the situation in Uganda / Africa and the Netherlands, followed by more generic conclusions.

### 7.3.1 Uganda / Africa

1. *Recognition of the informal seed system alongside the formal seed system.* Some developing countries carefully balance the rights of breeders and farmers and intend to create suitable incentives for commercial sub-sectors in agriculture, while avoiding negative impact on resource-poor farmers. For example, Ethiopia is preparing a Proclamation where different levels of protection are provided for different sub-sectors of agriculture, thus protecting export-oriented horticulture with IPRs at international levels, providing breeder's rights for commercial seed crops and full farmers' rights with respect to handling of seed for resource-poor farmers. (Chapters 3)

2. *Plant Breeder's Rights may – when carefully framed and implemented -- support the uptake of new varieties in the product portfolio of a seed enterprise, where otherwise the variety might be left 'on the shelf'*. Seed companies are likely not eager to take the risk of introducing a new variety into the country – or bear the cost of the necessary investments in demonstrations and advertising without some exclusivity. In Uganda, NARO provides that through exclusive provision of breeder's seed. Plant Breeder's Rights could operate in a similar way. However, if these rights obstruct the local exchange of such seed, the objective of reaching resource-poor farmers will not be met. (Chapter 2)

3. *International research agencies and some donors investing in agricultural research provide safeguards for access to new varieties*. The Alliance for a Green Revolution for Africa (AGRA) for example requires that agricultural innovations generated through research supported by AGRA ought to be made available for further research and development. The African Agricultural Technology Foundation (AATF), which deals exclusively with proprietary agricultural technologies, requires that innovations arising out of its support be accessible to resource-poor farmers. These approaches provide useful insights into how IP can be harnessed to address technological constraints to smallholder agriculture. However, policies of the largest organization for international agricultural research (the CGIAR) towards the production of international public goods are being reformulated and it is as yet unclear what the future will bring. (Chapter 4)

### 7.3.2 The Netherlands

4. *By having co-ownership over the IP resulting from the research it financed, the Directorate-General of International Cooperation (DGIS) was able to co-decide on its use and secure its availability for development purposes*. As a co-owner, DGIS could set conditions on how IPRs were managed and transferred, for example by demanding the inclusion of a humanitarian license when the IP was transferred to a third party. This policy has, however, been abandoned. (Chapter 5)

5. *The Incentive Fund for Open Access Publications established by the Netherlands Organization for Scientific Research (NWO)*. Through this 5 million euro fund every NWO project has a budget for publishing in open access journals or purchasing the rights for open access of an article. This initiative can strongly improve the accessibility of Dutch

scientific knowledge for libraries and research organizations in developing countries. (Chapter 5)

6. *There are some recent voices calling on the Dutch government to create more synergy between the, up till now, organizationally divided worlds of international development policy and research and innovation policy*. For example, the Advisory Council for Science and Technology Policy (AWT) has advised the Dutch government to make global challenges a *leitmotiv* in setting the national research and innovation agenda, that research organizations take up these global challenges in cooperation with partners in developing countries, and that new arrangements are sought in the field of IP protection that facilitate international development. This has also been discussed in WOTRO, the NWO branch for development-oriented research (Chapter 5)

### 7.3.3 General

7. *There already exist several well-established provisions in national IP laws and/or international treaties that promote the accessibility and transfer of protected materials for specific groups or purposes*, namely:

   i. *Farmers' rights*. Farmers' rights refer – among other issues – to the right of farmers to save, exchange and sell farm saved seed. The farmers' privilege in Plant Breeder's Rights has, however, gradually been restricted over the past 50 years in subsequent Acts of the UPOV Convention. Chapter 1)
   ii. *The breeder's exemption*. The breeder's exemption holds that a variety that is protected by Plant Breeder's Rights can be used as starting material for the development of a new variety. (Chapters 1 & 5)
   iii. *The research exemption*. The research exemption in patent laws allow for the use of patented inventions in scientific research. Yet, this exemption is rather restricted in most patent laws, allowing merely research "on" the invention and not "with" it in order to develop a new invention or product. (Chapter 5)
   iv. *Compulsory licenses*. A compulsory license is an authorization by a government to use or manufacture an IP protected invention without permission of the right holder. This is only to be applied under specific conditions and there are few examples of its use for aid or development purposes. (Chapter 5 & Part 1)
   v. *Disclosure condition in patent law*. A fundamental requirement of patent law is the disclosure of the patented invention so that a person 'skilled in the art' can reproduce it. Patent databases contain therefore a valuable source of information. (Chapters 5 & 6)

8. *There are several humanitarian licensing tools that can secure and facilitate the accessibility or transfer of IP-protected knowledge, materials and technologies for development purposes*. Humanitarian licensing is a generic term for all kinds of contract clauses and licensing forms that protect the possibility for inventors and technology suppliers to share their IP with people in need, or with organizations who work to support those in need. Normally, they set the conditions for the provision of access to innovations on a royalty-free basis or at a reduced cost in specific countries or for

specific groups or applications. In this way, such licenses can ensure that knowledge and technologies stay available for humanitarian use while maintaining the incentive function of exclusive IP-rights for other parties. Open-source licensing is another tool that aims to protect the ability to use and improve technologies and materials by demanding that every user subscribes to the same open-source conditions. (Chapters 4, 5 & 6)

9. *Several solutions have been proposed in order to counteract the blocking effect of patents on the availability of genetic material for further breeding*. Proponents of the Plant Breeder's Right system favor the inclusion of a breeder's exemption in patent laws. Others have proposed to establish sector agreements that allow breeding with patented varieties as long as the new varieties do not contain the patented traits anymore. Other proposals relate to reducing the level of strategic patenting by patent holders, and the implementation of stricter guidelines for patent offices to improve patent quality. (Chapter 6)

10. *The development of an effective IP system in developing countries can encourage foreign parties to enter their markets, or to share their technologies with research partners in these countries*. Many research organizations and companies from the developed world only want to collaborate with partners in developing countries when they can be sure that their technologies are protected and managed. Such national policies will at least reduce the level of uncertainty. (Chapter 6)

## 7.4 Recommendations

Given the findings that resulted from this research project, we have formulated the following recommendations on how the relationship between IP and development (achievement of MDG 1c) can be improved. Our recommendations relate specifically to the various IP policies and practices evaluated, and are structured again with respect to their relevance to the situation in Uganda / Africa and the Netherlands, followed by more general recommendations that particularly concern the organizations responsible for IP policymaking on the international level.

### 7.4.1 Uganda/ Africa

1. *If Uganda and other African countries are to support poverty reduction through research for development, it should formulate more tailor-made IPR laws that take into account the need for farmer-to-farmer technology transfer.*

2. *Public research organizations in Africa need to frame their institutional policies in such a way that both commercial and (near-) subsistence agriculture of the country can be supported. They should increase their capacity in IP-management in order to avoid concluding contracts that are not to the benefit of the country as a whole or the poorer constituency of farmers.*

3. *African countries should actively pursue the integrated seed system development pathway that recognizes the importance of farmers' seed systems next to the formal system on a crop-by-crop basis.*

4. *Uganda should increase its policy coherence relevant to seeds and IPRs by making sure that the various institutions involved and their mandates are properly coordinated.*

### 7.4.2 The Netherlands

5. *The Dutch government should create much more synergy between its research and innovation policy and its international development policy.* Part of this is:

   i. *The development of a coherent IP policy with respect to public research*. With attention to access to technology for development purposes, such as humanitarian use licenses, open access (publications), and a breeding specific amendment of the research exemption in patent law.
   ii. *An evaluation of the current research funding system*. With regard to development aspects of basic funding, co-matching, and funding conditions that relate to IP.

6. *Develop criteria and incentive mechanisms for valorisation that go beyond mere economic outputs and reach across borders*. The development of criteria that can evaluate non-economic results and applications of public research can create a context in which international development outputs can be recognized and stimulated.
7. *Build more expertise and capacity with respect to humanitarian licensing strategies at public research organizations and funding agencies*. Dutch organizations can link with international initiatives (e.g., Global Access in Action) and develop a clear IP policy in this area.

### 7.4.3 General

8. *Evaluate the current patent system on a global level*. Investigate the need and consequences of including a breeder's exemption in patent law, potential mechanisms to curtail strategic patenting, and possibilities to improve the system's efficiency and bring down costs.

9. *Secure, strengthen and apply existing flexibilities in IP laws and international IP treaties*. Especially with regard to provisions on farmers' rights, the research exemption, and compulsory licenses, either within the existing rules or possibly as part of the process towards a new UPOV Conference to replace the 1991 Act.

10. *Investigate the expansion of the 'private and non-commercial use' exemption in plant breeder's rights to all resource-poor farmers*.

11. *Pay attention to IP mechanisms that can facilitate technology transfer for development purposes in international treaties and policies*. For example, reference can be made to humanitarian licensing strategies in relation to TRIPs Article 66.2, or in policy

documents such as the European Commission's Community Framework for State Aid for Research, Development and Innovation.

12. *Develop international policy with respect to ownership of and access to biosafety dossiers in relation to generic competition in agricultural biotechnology*.

## 7.5 Valorisation and Follow-up

The relationship between IP and the attainment of MDG 1c targets is not well explored in existing studies and there is scant literature on the subject. This research project aims to fill this gap, and it has been unique in that it covers a wide range of issues related to IPRs along the innovation chain from upstream research funding to use of new technologies by smallholders in Africa. It brought new light on a number of the related issues that deserve to be extended to a wider audience, both technical, legal and societal. In order to reach those audiences and to work towards the above recommendations, we have the following ideas and plans for valorisation and follow-up of this research project.

### 7.5.1 Uganda/ Africa

1. This report and a policy brief based on it will be presented to the Ministry of Agriculture, which is currently reviewing its draft seed policy, and its bill on Plant Breeder's Rights.
2. Together with the Uganda Seed Trade Association, a debate will be organized on appropriate levels of IPR in the sector. Some findings of this project were brought up during a meeting in Uganda organized by the African Union Commission Secretariat and Wageningen UR in March 2011 with representatives from government, private sector and non-governmental organizations.
3. The issue of IPRs has been tabled at a meeting of the African Seed and Biotechnology Programme of the African Union and FAO, Addis Ababa, May, 2011 involving six African countries and a number of regional commissions. The project leader has already made arrangements to this effect. It would be useful to extend this to other countries in the region, but funds are currently limited.
4. The results of the study will be presented to the Network of IP-Professionals of the Central Advisory Service on IP of the CGIAR ("the National Partners' Initiative") during its annual meeting – scheduled in September 2011.

### 7.5.2 The Netherlands

5. This report and a policy brief based on it will be presented to the Directorate-General of International Cooperation (DGIS) of the Ministry of Foreign Affairs, and will be widely distributed among the management of all organizations that have been contacted in the course of this research project, and to the ministries and organisations consulted in The Netherlands.
6. The results of the project will be included in the work plan of a research project sponsored by NWO on "Intellectual Property Regimes for Pro-poor innovation in agriculture" under its Responsible Innovation Program.

7. A research proposal has been granted by the Centre for Society and Genomics on a project to develop criteria and incentive mechanisms for valorisation of agricultural research beyond the needs of the Dutch society, across borders.
8. Aspects of the project already have been included in the curriculum on "IPRs in the Life Sciences" of Wageningen University. It is the intention to expand this education initiative.
9. The project results will be included in international mid-career training programs of the Centre for Development Innovation in Chennai (2011) and Wageningen (2012). There is also an interest from a SIDA-funded training program on Genetic Resources and Intellectual Property Policy course that will be held in Alnarp, Sweden and Nairobi, Kenya this year.

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# PART III

# AFFORDABLE HIV DRUG RESISTANCE TEST FOR AFRICA (ART-A) INTELLECTUAL PROPERTY

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## CONTENTS

# CHAPTER 1 RESEARCH QUESTIONS AND METHODOLOGY

## 1.1 Introduction

Understanding both the enabling and limiting factors of intellectual property rights in improving access to knowledge for those who can most benefit from it, is of key importance if the Millennium Development Goals (MDGs) are to be obtained. The key objective of Millennium Development Goal 6 (MDG 6) is combating the HIV epidemic, malaria and other diseases.[1]

In this study, we examine a unique European and African research consortium called the Affordable Resistance Test for Africa (ART-A) that was established to develop technologies for affordable HIV drug resistance testing in Africa.[2]

This consortium is a public-private partnership (PPP) and presents a great opportunity to study international, regional and institutional intellectual property laws and policies and how they affect access to knowledge and health innovations in Africa. Here we investigate the intellectual property landscape of this consortium in an attempt to identify how data and research output can be shared and protected by the consortium, and how consortium IP can be managed.

Medical diagnostics which rely on testing of genetic information have unique IP challenges as evidenced by ongoing debates around gene patenting.[3] In this context we explore suitable IP protection models that could be used by public-private partnerships that are developing medical diagnostic technologies to facilitate broader access to diagnostic testing in Africa. This also provides the opportunity to highlight barriers or opportunities created by IP regulation, legislation, enforcement and implementation to inform policy-makers and funding organizations into the future.

In this study of ART-A we review institutional, national and regional IP policies, strategies and legislation that have relevance to and that could influence the ability of the ART-A research consortium to make its technology accessible to end users in Africa.

## 1.2 Aim of the Research

The aim of the study is to develop IP management recommendations that are appropriate for and that support the aims and objectives of the ART-A consortium's research program. It describes the IP environment and develops recommendations that seek to find the right balance between the private sector's need for IP protection and the public interest of making knowledge freely available for the benefit of all, especially developing countries. The end goal is to ensure that products and services developed by the ART-A research consortium can be successfully produced and effectively used in combatting the HIV epidemic.

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1 Millennium Development Goals [online]. <http://www.undp.org/mdg/basics.shtml>.

2 Affordable resistance test for Africa [online]. <http://www.arta-africa.org/>.

3 Carbone, J., Gold, E. R., Sampat, B., Chandrasekharan, S., Knowles, L., Angrist, M. and Cook-Deegan, R. (2010), pp. 784-791.

### 1.3 Objectives of the Research

In order to achieve the above aim, the objectives of the project are to:

- Examine the role of European and African institutional collaborations in the generation of knowledge and IP within the consortium.
- Review the different forms of IP generated by the consortium and consider the legal and good practice mechanisms to ensure that the objectives of the consortium are achieved.
- Identify IP models or solutions designed to ensure that ART-A technology in particular, and innovative research in general, can be applied in practice to address the MDG 6.

It is intended that this research will inform the ART-A program, the WHO's Global Strategy for Prevention and Assessment of HIV drug resistance[4] and other similar public-private partnerships of important intellectual property related issues. This includes informing practices that should be implemented and also agreements that may affect or may need to be put in place, to ensure the knowledge developed by such research consortia can reach clinical practice. The ultimate goal is to assist doctors, laboratories and thereby patients, particularly those who depend on public health services for their healthcare.

### 1.4 Research Questions

The leading research questions that the project attempts to address are:

1. What is the role of IP in the ART-A project in its fulfilment of MDG 6?
2. How can data and research output be shared and protected in a manner that promotes development?
3. How should existing and newly developed IP of the ART-A public-private partnership be managed?
4. How can the process concerning the transfer and sharing of IP between consortium members be formalised?
5. What are suitable IP protection and management models for this international public and private partnership to facilitate affordable access of the technologies developed by the consortium?

### 1.5 Data Collection

The main source of information is the internet, which was used to access published papers, textbooks, book publications, legal documents, reports and general information. All material collected and used in the project is referenced in the report.

In addition, meetings were conducted with key people responsible for research work in the ART-A collaboration and intellectual property management, policy and strategy development at a regional and national level.

[4] Bennett, D. E., Bertagnolio, S., Sutherland, D. and Gilks, C. F. (2008), pp. 1-13.

### 1.6 Selection of Study Countries

The two African countries where ART-A research is being conducted to develop methods and protocols for HIV drug resistance testing are South Africa and Uganda. It is likely that only these two countries will be involved in any IP development related to ART-A and therefore these were the countries in Africa that were selected for this study. South African institutions are involved in both the development and evaluation of methods in centralised laboratories and those in Uganda are involved specifically in evaluation of the methods in remoter laboratories and clincal settings. These two countries also represent quite different levels of industrial development and have significant differences in their absorptive capacity for technology, as well as their capacity to innovate. Uganda is classified by the United Nations as a least developed country (LDC),[5] with different opportunities and challenges with respect to IP, as opposed to South Africa which is regarded as a developing or middle developing country.

In the longer term, the technologies developed will be deployed in laboratories in at least six African countries that have been supported by a larger capacity building and research program called PharmAccess African Studies to Evaluate Resistance (PASER).[6] These additional countries include Kenya, Zambia, Zimbabwe, and Nigeria.

### 1.7 Key Deliverables

The planned deliverables and outcomes of the project are:

i. **Improved contracting efficiencies.** In collaboration with sub-project 1 (see Part I), assess the influence of international treaties and conventions on European-African research collaborators of the ART-A consortium.In addition, to review consortium agreements for coherence, proper integration and practical application. The purpose of this exercise is to identify the key components of these agreements in relation to the protection and management of IP to serve other African projects where IP is a critical component.

ii **Better IP transparency and Freedom to Operate (FTO).** Using ART-A as an example, to make recommendations for handling issues relating to infringement and licensing options.

iii. **Exit strategies.** To provide exit strategy options for the consortium and address issues relating to IP ownership, maintenance and options for facilitating access to IP in Africa at the conclusion of the project.

iv. **Information dissemination.** Produce an end-users chapter that is customized for policy-makers, entrepreneurs and (academic) institutions. This chapter is the basis for two information dissemination workshops in Europe and Africa, to be organized in after completion of the final report.

v. **Develop practical IP management tools.** Where patented IP is generated by consortium members and needs to be managed to facilitate technology utilization, different options are considered and presented. Each option has its strengths and weaknesses and furthermore, non-IP related issues are also considered, like licenses, as well as regulatory, technical and capacity limitations.

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5 UN-OHRLLS [online].<http://www.unohrlls.org/>.

6 PharmAccess Foundation [online] <http://www.pharmaccess.org/Default.asp?Page=126>.

# CHAPTER 2 ART-A, MDG 6, AND IPRS

## 2.1 Introduction

This chapter examines global efforts to address poverty through the accomplishment of the Millennium Development Goals and explains how the ART-A project is linked to this global framework for poverty elimination. The chapter introduces the MDGs and indicates which targets in specific Goals apply to the ART-A initiative. A key objective of the ART-A project is to ensure that the technology being developed by the research consortium is available and accessible to laboratories that will use the tests developed to guide clinicians in the treatment of HIV-infected patients in the developing world.

The issue of access to medicines is influenced by an array of determining factors that include national legislation and regulations, intellectual property rights policies and laws, conditions set out in bilateral and international trade agreements, the level of investment and collaborative efforts by private and public sector partners and so on. Certain determinants may have more influence over others depending on the legal and regulatory conditions, resource capacity and policy conditions that exist in different developing countries. In order to develop a sustainable technology transfer solution for the HIV drug resistance testing technologies, the ART-A project needs to understand these determinants, their application and effect.

## 2.2 MDG 6: Reversing the Spread of HIV and AIDS, Malaria and TB

Of the eight MDGs described in the United Nations Millennium Declaration, the ART-A project specifically focuses on those goals that relate to healthcare, namely MDG 6 in relation to target 6c: by 2015 to halt and begin to reversing the incidence of malaria and other major diseases. The work of ART-A also has relevance to MDG 4, reducing under-five mortality by two-thirds; and MDG 5, reducing maternal mortality by three-quarters. However, MDGs 4 and 5 are not the focus of this pilot project.

The 2010 MDG report reveals that the spread of HIV appears to have stabilized in most regions and more people are surviving longer.[7] That said, Sub-Saharan Africa remains the most heavily affected region with 72% of all new infections taking place in this area in 2008.[8]

According to the MDG 2010 report, there are remarkable improvements in key interventions, such as in HIV drug treatment. Between 2003 and 2008, the number of people receiving antiretroviral therapy increased tenfold from 400 000 to 4 million, corresponding to 42% of the 8.8 million people who need treatment for HIV. However, the rate of new infections continues to outstrip the expansion of treatment measures. There is also the need to improve monitoring and evaluation systems. To this end, accurate monitoring of drug resistant HIV is critical.

In respect of MDG 6 specifically, the MDG Africa Steering Group report identifies the following select activities as achievable by 2015 provided there is adequate intervention.[9]

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7 The Millennium Development Goals (2010) [online]. New York: United Nations (UN). <http://www.un.org/millenniumgoals/pdf/MDG%20Report%202010%20En%20r15%20-low%20res%20100615%20-.pdf> (Accessed 08 August 2010).

8 Idem.

- Widespread access to comprehensive primary health systems including:
  - Adequate human resources for the management and provision of health services
  - Adequate access to essential commodities
  - Adequate supply and logistics system
  - Appropriate infrastructure and equipment.
- Universal and free access to HIV /AIDS prevention, mitigation and treatment by 2010.

The potential of the technologies such as the ones being developed by the ART-A project, assuming they can be applied in Africa, is important to improving the standards of HIV treatment monitoring. It is in this context that the study of the ART-A IP environment, by addressing the influence of IP on the costs, access and freedom to operate of ART-A technologies, addresses MDG 6 within the greater Sharing Knowledge for Development initiative.

### 2.2.1 Access to Healthcare

It is widely recognised that health is central to breaking the cycle of poverty and is essential to both social and economic development. An improved health status leads to increased productivity and performance, greater life expectancy, increased economic activity, and ultimately, greater social and political stability. Globally, there have been significant advances in health, science, and technology.[10] Health infrastructure has greatly improved; public health interventions and socio-economic development have reduced mortality and raised life expectancy; and, healthcare systems have improved their efficiencies by harnessing the latest technologies.[11] That said, these advances have not been experienced by all. It is estimated that only 10% of the resources spent on global health research are directed towards conditions that affect people with the greatest burden of disease.[12]

### 2.2.2 Public-Private Partnerships

Public-private partnerships (PPPs) have been explored as a mechanism to mobilise resources and support for health development activities, particularly in under-resourced developing countries. PPPs, including governmental agencies, academic institutions, private industry, and not-for-profit organizations are being increasingly encouraged as part of the comprehensive socio-economic development framework[13] and are showing to be an effective model for tackling major public health issues. The inability of the public sector to provide for the public good efficiently and effectively due to a lack of resources, inadequate infrastructure and inadequate human capacity, has led to the emergence of PPPs. These have been

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9 Millennium Development Goals Steering Group Africa (2008). Achieving the millennium development goals in Africa: Recommendations of the MDG Africa Steering group. New York [online]. <http://www.mdgafrica.org/pdf/MDG%20Africa%20Steering%20Group%20Recommendations%20-%20English%20-%20HighRes.pdf> (Accessed 1 February 2011).

10 Augustine, A. and Anthony, Z. (2007), pp. 176-180.

11 Kaseje, D. (2006).

12 Idem; World Health Organization Medicines Strategy: Expanding Access to Essential Drugs (2002) [online]. 55th World Health Assembly, 28 March 2002.

13 Health (2010).

established to tackle particular health problems by targeting specific products, diseases or technologies. Private sector partners offer public benefit though the provision of resources, technical expertise or outreach. Such partnerships create powerful mechanisms for addressing difficult problems by leveraging on the strengths of different partners to improve the public sector's ability to fulfill its mandate.
PPPs involved in health-related sectors have different functions:[14]

i. **Product development** – these partnerships focus on pharmaceutical product development for diseases of importance to the developing world. Examples include preventive medicines such as vaccines and microbicides, as well as treatments for otherwise neglected diseases. These partnerships aim to fulfill the international public sector's commitment to health by harnessing industry's intellectual property and expertise in product development. Examples include the Global Alliance for TB Drugs (GATB), the Malaria Vaccine Initiative (MVI), the IAVI (International Aids Vaccine Initiative) and as will be described in detail here, ART-A.

ii. **Improving access to healthcare products** – such partnerships provide a mechanism to mobilise resources and support for health activities in resource-poor countries. Many of these partnerships focus on combating neglected diseases by facilitating access to healthcare and healthcare products. Examples include the International Project Finance Association (IPFA) which is driving PPPs in healthcare in South Africa and again, ART-A.

iii. **Global co-ordination mechanisms** – in these partnerships, international institutions act as channels for the disbursement and management of funding programs or may directly undertake research and/or health service provision. They are mostly funded through official development assistance but, in some cases, they also combine income from philanthropic foundations or business partners. Partnerships tend to focus on specific targets and diseases to bring greater efficiency and provide learning from good practice. The Global Fund for HIV/AIDS and Global Alliance Vaccine Initiative (GAVI) are examples of global coordination PPPs.

iv. **Strengthening health services** – these PPPs focus on building support for health service delivery. Such PPPs address capacity issues for healthcare provision, infrastructure and facilities. They also analyze strategic, regulatory and policy issues that could improve health delivery in developing countries. Examples include IFPA mentioned above and the ART-A initiative.

v. **Public advocacy and education** – advocacy partnerships are designed to highlight and promote action on key issues representing an area of unexploited potential for public-private collaboration. These partnerships concern themselves with increasing public attention and raising awareness on the plight of the poor in developing countries with the hope of increasing investment to address challenges. Public advocacy and

[14] Dhaene, G. (2008).

education PPPs include the African Malaria Partnership and the Global Coalition on HIV/AIDS, Tuberculosis and Malaria.

vi. **Regulation and quality assurance** – the purpose of these partnerships is to provide training, capacity building and support to improve the efficiency and effectiveness of regulatory systems in developing countries. Organisations such as the UK Department for International Development (DFID), United States Agency for International Development (USAID) and the International Finance Corporation (IFC) are active in these roles.

Typically, PPPs fulfill several roles and therefore address one or more of the above mentioned features and functions. Supporters of PPPs believe that such partnerships help address specific cost and investment challenges faced by governments and contribute to better efficiency and quality of health services. By so doing, they are of the view that PPPs play a part in improving equity in access to essential drugs while enhancing research into some of the world's diseases that predominantly affect the poor.[15] Harmony with national health priorities is important and therefore, the partners need to work closely with local governments and health authorities. Public-private partnerships can be complex, with several organizations driving multiple, interdependent outcomes. It is necessary to map out the scope and roles of each partner and to agree on resources and responsibilities. Performance monitoring is essential in ensuring that the partnership meets its goal.

An additional benefit of PPPs is in addressing market failure. Drug and vaccine development is capital intensive and highly risky. Commercial drugs such as those for diabetes, oncology, or cardiovascular disease can generate significant profits and therefore, pharmaceutical companies are able to offset economic investments. [16] The same does not necessarily hold true for drugs and other health technologies developed for diseases predominantly found in developing countries. As a result, pharmaceutical companies are unable to generate attractive returns on investments because commercial markets do not exist to offset the risk of developing these drugs. Therefore, public sector participation is necessary to lower the investment risk associated with developing new entities for diseases that mainly affect the poor.

### 2.2.3 Regulatory Issues

With the growing demand for rapid registration of new and more complex drugs, the challenge is to assess the quality, safety and efficacy of these medicines submitted for marketing approval.[17] The processing and interpretation of complex clinical trial efficacy and safety data is greatly constrained by the limited organisational and scientific capacity of drug regulatory authorities in developing countries. Registration can take several years, and is vulnerable to lobbying from interest groups. Regional harmonization efforts have the potential to ease capacity bottlenecks, but are also technically complex. The links between

[15] Dlamini, Q., Lush, L., Auton, M. and Nkandu, P. (2004).

[16] Marden, E. (2010), pp. 217-266.

[17] Nishtar, S. (2004), p. 5.

data protection, drug registration requirements, exclusive rights to marketing and access to medicines should be carefully considered and fully understood in order to optimise policy development and decision-making. Other challenges are that institutions responsible for drug regulation are poorly funded and resourced. They often lack skilled capacity to carry out their mandates and inspect registration dossiers and provide quality assurance in an efficient and effective manner. Lastly, enforcement mechanisms are not in place to monitor defiers.

The challenges with regulatory bodies in Africa exist in both Uganda and South Africa. With the exception of electromagnetic medical devices, South Africa's medical device market is poorly regulated. To address this, South Africa is planning to launch a full regulatory system for devices and diagnostics which will be implemented in 2011. Similar changes are expected in Uganda. In September 2009, Uganda's National Drug Authority issued guidelines for registering medical devices and is also developing regulations for the registration, importation and control of all medical devices.

Different laws and regulatory authorities usually govern medicines regulatory issues and intellectual property rights.Therefore, regulatory authorities need to interface with those concerned with the country's intellectual property rights issues. An effective national medicines registration authority must be in place to allow for the effective operation of compulsory licenses and parallel trade. If health, patent and medicines regulatory authorities are not working closely together, the potential benefits of the TRIPS flexibilities may not be realised.

Access to medicines is a multi-dimensional issue and no one factor can be said to be solely responsible for, or to have a direct impact on, impeding access to medical technologies. A holistic approach is required. As the ART-A collaboration makes progress in the research and development area, it will need to pay attention to the above issues regarding access to health technologies if it is to fulfill earlier its objectives of developing effective HIV treatment monitoring tools that are accessible, appropriate and affordable, especially to the poor in the developing world.

### 2.2.4 Access to Healthcare in Africa

Large disparities exist in Africa where access to new health technologies and healthcare is unequal.[18] African countries are constrained by resource scarcity resulting in extreme stress being placed on the existing health facilities and infrastructure. In addition, Africa is disproportionally affected by widespread poverty, a high burden of diseases that are a challenge to address, high mortality rates and a decrease in human resource capacity due to diseases, war, immigration of foreign nationals and the loss of healthcare workers via emigration to "greener pastures". Whether one talks of the least developed countries in Africa or the more advanced developing economies such as South Africa, the impact of these challenges is devastating across the board.

Many Africans are in a vicious cycle whereby their poverty-stricken situation disempowers individuals to access nutritious food, healthcare and health products.[19] As a result, such individuals are more susceptible to ill health. Ill health decreases productivity and the ability to engage in income-generating activities. This leads back to poverty and so the

[18] Augustine, A. and Anthony, Z. (2007), pp. 176-180.

[19] Leach, B., Paluzzi, J. and Munderi P. (2005).

situation perpetuates itself. It is against this backdrop that the ART-A collaboration is seeking to provide affordable assays for monitoring the efficacy of HIV treatment and the emergence of HIV drug resistance. Given the extremely high prevalence of HIV in Sub-Saharan Africa and the high impact of the disease on social, economic and political stability, the need for such assays is critical.

### 2.3 IP and Access to Health Technologies

Much has been written about the role of intellectual property and the impact of IP rights on the availability of and access to health technologies and health-related information.[20] There are those who believe that IP rights ownership is essential for fostering and stimulating innovation and is a critical element for development. Equally, there is another group that is of the opinion that IP and in particular, patents, inhibit access to much-needed drugs, diagnostics and vaccines amongst the poor, and that the patent system does more harm than good for developing countries. According to the draft paper 'Human health and the IP system: Innovation, access and public welfare' published by WIPO, the overarching public policy role of the patent system is twofold:[21]

i. **To promote innovation,** through garnering and directing resources towards beneficial research and development that is a genuine and practically useful addition to technological knowledge.
ii. To provide **a transport mechanism for the dissemination and accessible publication of this innovation,** and the practical, equitable availability of the fruits of innovation.

In carrying out its research activities, ART-A is involved in generating new IP. However, the generation of IP is a secondary goal to the provision of an affordable HIV drug resistance testing protocol that can be widely used in Africa. The IP therefore is not a commercially driven incentive but rather, innovation-driven and the objective is to provide access to an essential health technology. That said, to ensure freedom to operate, ART-A is compelled to consider IP protection.

According to the same WIPO paper, the patent system can be simplified to say that it addresses innovation and access and that much of the current debate about patents and public health boils down to specific concerns about how to attain these twin goals in a balanced way at the level of principle and in practice.[21] The tensions have polarised to a public versus private sector issue. Exclusive IP rights are seen to represent private sector interest to the detriment of public interest, such as essential health products and crucial research technologies and research tools. This, as a result, is believed to hold back innovation.

Studies that look at the relationship between patents and access to essential medicines show that in 65 low- and middle-income countries, where four billion people live, patenting is rare for all but 19 of 319 products on the WHO's Model List of Essential Medicines.[22] Only seventeen essential medicines are patented and therefore, the overall incidence of patenting is low and concentrated in larger markets. This suggests that patents in respect of the WHO's

[20] Kaseje, D. (2006); Marden, E. (2010), pp. 217-266; United Nations (2010); Ford, S. (2001), p. 15.

[21] WIPO (2007).

[22] Laing, R. (2011).

list of essential medicines are not the only factor that influence access. Rather, access to medicines and medical technologies are affected by the many other factors such as human resource inadequacies, basic health infrastructure deficiencies, weak political will and inadequate incentive structures for the promotion of research and development. In many cases, countries and their populations simply cannot afford the drugs even if they were produced and supplied at cost.In 2008, the World Health Organisation adopted a Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property.[23] The strategy proposes that, as part of its mandate, the WHO should play a strategic and central role in the relationship between public health innovation and intellectual property with the goal of promoting new thinking in innovation and access to medicines. The Global Strategy is driven by WHO's Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG)[24] and the role of the IGWG was to implement the recommendations presented in the report of the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). The work of the CIPIH was to review the interfaces and linkages between intellectual property rights, innovation and public health in light of current evidence and examine in depth how to stimulate the creation of new medicines and other products for diseases that mainly affect developing countries. The assessment took into account how intellectual property rights can promote innovation relevant to public health, and how funding and other incentive mechanisms, including institutional arrangements, may contribute to this outcome. One of the recommendations of the CIPIH report is that WHO should develop a Global Plan of Action to secure enhanced and sustainable funding for developing and making accessible products to address diseases that disproportionately affect developing countries.[25] It is this recommendation that forms the basis of future actions of the Global Strategy. The Global Strategy is a landmark agreement as it aims to improve treatment for poverty-related and neglected diseases that disproportionately affect developing countries, both by simultaneously stimulating innovation to find new products for these diseases, and by improving the availability, affordability, accessibility and acceptability of existing products. The eight elements of the Global Strategy are designed to promote innovation, build capacity, improve access and mobilise resources. They are:

1 Prioritizing research and development needs
2. Promoting research and development
3. Building and improving innovative capacity
4. Transfer of technology

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[23] World Health Organization project on improving access to medicines in developing countries through local production and related technology transfer (n.d.) [online]. <http://www.who.int/phi/documents/TechnologytransferactivitiesforElement4.pdf> (Accessed 02 August 2010); *Putting the GSOPA into action at country level proposed approach and tools* [online]. <http://www.who.int/phi/documents/InnovativeframeworktosupportimplementationoftheglobalstrategydevelopedbyCOHRED.pdf> (Accessed 02 August 2010]).

[24] World Health Organization. Public health, innovation and intellectual property [Online]. <http://www.who int/phi/en/> (Accessed 03 February 2011).

[25] Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) [Online]. <http://www.who.int/intellectualproperty/documents/thereport/questions/en/index.html> (Accessed 03 February 2011).

5. Application and management of intellectual property to contribute to innovation and promote public health
6. Improving delivery and access
7. Promoting sustainable financing mechanisms
8. Establishing and monitoring reporting systems.

As far as implementation of the Global Strategy is concerned, member states are required to implement the specific actions recommended in the strategy and to actively support wide implementation by providing adequate resources. The WHO has overall responsibility of monitoring implementation by member countries.

The African Network for Drugs and Diagnostics Innovation (ANDI) established by the WHO through the Special Programme for Research and Training in Tropical Diseases (TDR) is another WHO initiative designed to promote African-led health product innovation to address public health needs through research networks.[26] ANDI's goal is to discover, develop and deliver affordable new drugs, vaccines, diagnostics and other health products that fight and prevent diseases that affect the African continent. The ANDI initiative accomplishes its goals through partnering, funding and coordinating research and creating collaborative project networks and partnerships among African research institutions. One of ANDI's targets is to establish platforms to help manage pharmaceutical research throughout Africa.

UNCTAD has established an IP program that conducts research and analysis on trade and development aspects of intellectual property. [27] According to UNCTAD, the IP program seeks to help developing countries participate effectively in international discussions on intellectual property rights and at the national level, to help ensure that their IP policies are consonant with development objectives. UNCTAD is responsible for producing country specific reports on the Development Dimensions of Intellectual Property. These reports provide a number of policy recommendations on how to implement international intellectual property obligations coherently with other domestic public policies, such as the transfer and dissemination of technology and knowledge, as well as the promotion of access to medicines and textbooks in a pro-competitive environment. The Development Dimensions of Intellectual Property in Uganda Report together with UNCTAD's joint project with the International Centre for Trade and Sustainable Development (ICTSD) on Intellectual Property Rights and Sustainable Development intended to address the concerns voiced by developing countries with respect to the implementation of the TRIPS Agreement and new developments in the area of intellectual property rights (IPRs) contained in multilateral treaties and regional and bilateral free trade agreements. The project aims to achieve this by improving the understanding of IPRs in relation to development and helping national entities with IPR-related policies and implementing international IP commitments.

### 2.3.1 TRIPS Agreement and Public Health

While the Doha Declaration was hailed an important milestone for access to affordable medicines by the poor, concerns still remain regarding the impact of intellectual property

[26] United Nations Conference on Trade and Development (UNCTAD) [Online]. <http://apps.who.int/tdr/svc/publications/tdrnews/issue-81/african-network> (Accessed 03 February 2011).

[27] TDR for research on diseases of poverty [Online]. <http://www.unctad.org/Templates/StartPage.asp?intItemID=3423&lang=1> (Accessed February 03, 2011).

rules on the affordability and therefore access to medicine. As described in PART II of this full report, there are many opposing views regarding the suitability of the TRIPS Agreement legislation in respect of developing countries.[28] The TRIPS Agreement provides minimum standards for intellectual property law procedures and remedies, that should be available to rights holders who can enforce their rights effectively. It establishes intellectual property standards for WTO members and is historically based on the standards of the developed countries.

The TRIPS Agreement requires patent protection for all products and processes with a minimum duration of 20 years from the original date of filing. No special considerations are granted for pharmaceuticals. The agreement permits members some discretion in enacting and amending their laws and regulations, which can help promote public health goals. Therefore, when developing countries establish standards of patentability for pharmaceuticals they should consider the implications of those standards. Standards which are too broad may lead to inappropriate extension of patent life beyond the period required by TRIPS and those which are too narrow might not be TRIPS compliant.[29] It is believed that WTO free trade provisions can stimulate generic competition and reduce the prices for off-patent drugs.However, TRIPS may also significantly delay the introduction of new generic drugs, depending on the way national legislation is designed and implemented. Therefore, developing countries need to be cautious about enacting legislation that is more stringent than the TRIPS requirements and are cautioned to create IP laws that are relevant and appropriate to their needs.

**Box III-1:** ***The TRIPS Agreement: Implications for the IP Laws in Uganda***

*As a result of the activities of the Uganda Law Reform Commission and the TRIPS Task Force, there are a number of bills and draft bills in the pipeline targeting provisions relating to IP rights administration and enforcement. These are intended to update the Ugandan law to bring it in line with the country's international obligations under the TRIPS Agreement. Like other least developed countries, Uganda has until 2016 to amend its laws to comply with the provisions of the TRIPS Agreement.[30] The following is a sample of such pieces of legislation that are in the offing:*

***The Industrial Property Bill, 2001.***

*This bill provides for the promotion of inventive and innovative activities to facilitate the acquisition of technology through the grant and regulation of patents, utility models, technovations and industrial designs. The revised bill was tabled in Parliament in 2009 and if enacted into law, would modernise an important part of Uganda's regime of IP law. It covers all industrial property (patents, industrial designs, utility models, and technologies) except trademarks.*

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28 Teljeur, E. (2002); International Institute for Sustainable Development (IISD) (2003); Avafia, T. (2005); Williams, M. (2001); Musungu, S., Villanueva, S. and Blasetti, R. (2004); Elbeshbishi, A. (2007).Teljeur, E. (2002).

29 World Heath Organization. International Trade and Health: A Reference Guide. [Online] 2009. <http://www.searo.who.int/LinkFiles/IPT_ITH.pdf.> (Cited: October 15, 2010).

30 Article 66 of the TRIPS Agreement stipulates that least-developed country Members are not obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II (Standards Concerning the Availability, Scope and Use of Intellectual Property Rights) of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016.

***The Patents (Amendment) Bill, 2000.***

*The object of this bill is to amend the Patents Statute (No. 10 of 1991) to give effect in and by Uganda, to the provisions of the Patent Cooperation Treaty signed in Washington in 1970. Uganda is a party to this treaty. If the changes are effected, they will introduce provisions for processing by the Patents Registry in Uganda of international applications in accordance with an international system under the treaty whereby a single application made and filed in a country, party to the treaty, will have the same effect as an application filed in any other country party to the treaty. Patent applications are not examined by Uganda's patent office; instead, this function is carried out by ARIPO.*

**Box III-2:*The TRIPS Agreement: Implications for the IP Laws in South Africa***

*Due to the relatively advanced IP laws in the country, South Africa's transition towards TRIPS compliance was fairly straightforward. For the purposes of the TRIPS Agreement, South Africa was considered a developed country and therefore had until 1 January 2000 to adopt the required legislation to comply with TRIPS requirement.[79] In response, South Africa amended several IP–related Acts. Given that South African legislation was close to TRIPS compliance even before the amendments, the changes have not made a substantive impact.*

Developing countries argue that the TRIPS Agreement, which was derived from the developed world for its own benefit, is not appropriate for countries struggling to meet health and development needs.The reason is for this is that many developing countries lack an effective IP system, manufacturing capability and the ability to generate sufficient intellectual property for them to be able to apply the trade benefits that TRIPS offers.At the same time, they have to give protection to foreign-derived IP – foreigners therefore benefit. It is counter-argued that TRIPS has certain flexibilities built into the Agreement that member countries are able to take advantage of. The crucial flexibilities include, among others:[31]

- **Compulsory licensing:** the ability of the relevant authorities to grant and define when to issue a license to manufacture or import a generic drug without the consent of the patent holder, as long as the patent holder is compensated. The TRIPS Agreement provides countries with broad discretion to establish the conditions under which they may issue compulsory licenses and therefore, countries have "the freedom to determine the grounds upon which such licenses are granted."[32]
- **Exhaustion of patent rights:** the ability to decide when patent holders lose their exclusive right over the sale of drugs. This enables the importation of patented drugs from countries where patent rights are exhausted, meaning the purchaser can re-sell the product and therefore are less expensive (termed "parallel importation").

31 Mercurio, B. C. (2004).

32 Dowdeswell, B. and Heasman, M. (2004).

- **Exception to patent rights**: an example of such an exception is to allow national pharmaceutical companies to import, manufacture and test a drug prior to the expiry of the patent, in order to obtain regulatory approval, thereby ensuring that generic drugs can be quickly made once the patent runs out (termed "Bolar provision").
- **Prohibition of anti-competitive practices:** This provision countries the ability to penalise pharmaceutical patent owners that abuse their dominant position in contractual relations and engage in prohibitive pricing.
- **Government use:** the ability of the government, or an agent, to import, manufacture, supply or use a patent without the consent of the patent holder, as long as the patent holder is informed and compensated. This measure is important to supply national ARV access programs with cheap imported generic drugs.

The TRIPS Agreement raises some important questions for monitoring the public health impact. First, are newer essential drugs more expensive than they would have been if not under patent? Second, is the introduction of generic drugs being slowed as a result of applying TRIPS conditions? Third, are more new drugs for neglected diseases being developed? And, fourth, are transfer of technology and direct foreign investment in developing countries increasing or decreasing?

To respond to concerns expressed by developing countries and non-governmental organizations regarding the TRIPS Agreement and that it might make some drugs difficult to obtain for patients in poor countries, WTO member governments adopted the Declaration on the TRIPS Agreement and Public Health by consensus at the WTO's Fourth Ministerial Conference in Doha, Qatar held on November 14, 2001. [33] The Doha Declaration on the TRIPS Agreement and Public Health set out to clarify ambiguities in WTO intellectual property rules (TRIPS Agreement) about the ability of member countries to produce and import affordable drugs. It reaffirmed members' rights to "determine what constitutes a national emergency or other circumstances of extreme urgency", and "to determine the grounds" for granting "compulsory licenses" authorising the production of patented medicines without the consent of the patent holder. The TRIPS Agreement also allows members to invoke compulsory licensing in cases of public non-commercial use where the government or third parties authorised by the government can use a patent to address public health needs.

While the Doha Declaration sought to address several contentious aspects of TRIPS, it did not completely resolve the debate over patent protection in the developing world. The Doha Declaration left one important and highly contentious issue unresolved: the use of compulsory licensing exceptions to patent protection for countries with public health needs and insufficient or no manufacturing capabilities. Although the TRIPS Agreement permitted governments to use compulsory licenses as mentioned above, Article 31 (f) specified that the generic copies of patented drugs thus produced must be predominately for a country's domestic market. This rendered compulsory licensing useless for countries lacking sufficient pharmaceutical manufacturing capacity, no matter how severe their public health problems. Given that most African countries that genuinely need to make use of patent exceptions are economically troubled nations with insufficient or no manufacturing capabilities, the

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[33] *Doha Declaration on the TRIPS Agreement and Public Health* (2001) [online].Agreement and Public Health. Council for Trade Related Aspects of Intellectual Property Rights. <http://www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_trips_e.htm> (Accessed on 1 July 2011).

exceptions in TRIPS failed to satisfy the needs of those countries for whom exceptions were designed to benefit.

Paragraph 6 of the 2001 Doha Declaration mandated that members reach a solution on this issue. After protracted debate, a solution to the paragraph 6 mandate was established by creating a waiver to Article 31(f). The temporary waiver was agreed on 30 August 2003, and then in December 2005 it was agreed to make it a permanent amendment to TRIPS, though not enough countries have ratified to put the amendment into effect. This waiver allows nations with production capacity to export more drugs made under compulsory licenses to country lacking manufacturing capability. As a result both the TRIPS Agreement combined with the Doha Declaration now improve the mechanisms by which developing countries can fulfill their public health obligations and ensure access to cheaper drugs. That said, this paragraph 6 solution has only been used once.[34]

Developing countries are encouraged to use the policy flexibilities, especially compulsory licensing, to obtain cheaper generic drugs under their essential medicines policy. Even at the time, critics argued that the numerous requirements of the agreement in respect of trading locally produced medicines and diagnostics set an impracticably high bar for the legal importation of drugs produced under compulsory licenses. The so-called '30 August 2003 decision' implementing paragraph 6 of the Doha Declaration and the subsequent amendment to TRIPS in November 2005, was effectively a waiver of the requirement that medicines produced under compulsory license be largely restricted to the domestic market.[35] Of the 24 LDCs that are WTO Members from the region, only Rwanda, in the context of the paragraph 6 decision, has declared that it will not enforce pharmaceutical patents. Interestingly, it appears that none of the 36 Sub-Saharan Africa WTO members have taken any legislative measures either to implement the 30 August 2003 decision or to ratify the protocol amending the TRIPS Agreement.

So far, the waiver has been little-used and with little success. The first country to attempt to use the waiver is Rwanda, where in 2007 it applied to the WTO Council for TRIPS to import a fixed dose combination of ARVs from Canada. In turn, the Canadian generic drug manufacturer applied for and was granted a two-year compulsory license to export fixed-dose combination drugs to Rwanda.[36] What appears on the surface to be a simple transaction turned out to be a protracted and arduous process that eventually fell through for a number of reasons. First, the application process was too cumbersome to work effectively. Factors that contributed to the lengthy process include protracted processing of applications and the Canadian manufacturer needing to negotiate licenses with the various patent owners. In the end, the parties were unable to agree on a license and as a result, the manufacturer had to apply for a different exportation license in order to circumvent the license issues. Second, the Canadian generic manufacturer was producing for Rwanda only, making it economically impractical to be producing for export to a single country. Third, the two year time frame granted for the compulsory license was not enough for the manufacturer to recoup their

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34 Third World Network (2010); New, W. (2010). Intellectual Property Watch. 16 October 2010 [Online]. <http://www.ip-watch.org/weblog/2010/10/16/wto-paragraph-6-meeting-aims-at-improved-use-of-health-waiver/> (Accessed on 1 July 2011).

35 DOHA Declaration on TRIPS and Public Health 5 Years on (2006) [online]. <http://ictsd.org/i/ip/38975/> (Accessed August 02 2010); Musungu, S., Villanueva, S. and Blasetti, R. (2004).

36 Hestermayer, H. (2007).

investment. Furthermore, the two year period did not prove to be sufficient time to process the import application submitted by Rwanda.

Although in theory compulsory licensing offers a legal solution to patent protection for HIV/AIDS treatment, in practice it is difficult to exploit for the following reasons: [85]

- Generic manufacturers are limited to producing only the quantities predefined in each compulsory license. This curbs the large-scale production that is required to deliver drugs cheaply.
- Certain large pharmaceutical companies have indicated that countries that issue compulsory licenses may face repercussions, mainly through issues raised in bilateral agreements.

It is interesting to note that compulsory licensing is used more in the US and EU than in developing countries. This is due partly to the fact that many developing countries do simply not have the capacity to manufacture the high technology items that would be subject to the compulsory license (e.g., specific drugs or active pharmaceuticals ingredients), meaning that a complusory license is of no practical use in that country.[37]

To make the decision permanent, two-thirds of the WTO members need to approve. While this has not been achieved, the temporary waiver is in place with the same effect as if the permanent amendment were in place.

**Box III-3:*Uganda and HIV – IP Matters Relating to Access to Medicine***

*Uganda is often held up as a model for Africa in the fight against HIV and AIDS[38]. Strong government leadership, broad-based partnerships and effective public education campaigns all contributed to a decline in the number of people living with HIV and AIDS in the 1990s.*

*The cost of ARV treatment has dramatically decreased since the UNAIDS Drug Access Initiative of 1997-2000.[39] The most radical drop in prices came as a result of the import of generic ARV drugs from India in 2000. The competition created by the import of generic drugs has led to further price reductions on patented medicines under the UN Accelerated Access Initiative. According to research conducted by Oxfam in 2001, about 95% of the medicines used in Uganda are imported and 80% of these are generic drugs.[40] However, despite the drop in cost due to the import of generic ARV drugs, the price of treatment remained unaffordable for most Ugandans and in 2002 only 10,000 of the 600,000 people living with HIV/AIDS at the time, had access to life-saving drugs. This situation is recognised by the government of Uganda in its initial report to the Human Rights Committee.[41] The Ugandan pharmaceutical industry tried to address the problem by applying for a license from the Health Ministry and National Drug Authority to produce cheaper ARVs.[61] However, their application was rejected by the Health Ministry and National*

37 Reichman, J. (2009).

38 Averting HIV and AIDS (n.d.) [online]. <http://www.avert.org/aids-uganda.htm> (Accessed 01 September 2010).

39 *Implementation of the covenant on civil and political rights Uganda* (2004) [online]. <http://www.3dthree.org/pdf_3D/3DHRCUgandaBrief04en.pdf> (Accessed 01 September 2010).

40 *Uganda: Health ministry diverts ARV money* [online]. (2009) <http://www.plusnews.org/Report.aspx?ReportId=85658> (Accessed 02 September 2010).

41 *Implementation of the covenant on civil and political rights Uganda* (2004) [online]. <http://www.3dthree.org/pdf_3D/3DHRCUgandaBrief04en.pdf> (Accessed 01 September 2010).

*Drug Authority due to the risk that the drugs would be of insufficient quality. In order to make ARV treatment affordable for the most vulnerable groups in Uganda and comply with the right to life under Article 6 of the ICCPR (International Covenant on Civil and Political Rights) and the rights of the child under article 24 ICCPR, competition from imports of cheap generic drugs must continue and the capacity of Uganda's national pharmaceutical industry must be reinforced.*

**Box III-4:** ***Threats to Access to Medicines***

***Uganda***

*A threat to medicines access in Uganda is the Uganda Anti Counterfeit Goods Bill of 2010.The bill is expected to supersede all national legislation pertaining to counterfeit goods. It provides a wide and ambiguous definition of counterfeit goods which not only applies to trademark counterfeit and copyright piracy but also includes all other forms of intellectual property, such as patents and Plant Breeder's Rights. The TRIPS Agreement deliberately distinguishes between trademark counterfeits and copyright piracy and other forms of IPRs. One of the reasons leading to this distinction is because at the time of the negotiations members were aware that IPR infringement in a field such as patents is less obvious than in trademarks, and would therefore be subject to lengthy litigation that might even result in claiming the original patent invalid.[42,43] If Uganda's Anti Counterfeit Goods Bill were to be passed into law, it would affect access to life-saving medicines as it treats generic medicines as counterfeit goods. This would empower the Commissioner of Customs and the Uganda National Bureau of Standards (UNBS) to seize and detain medicines suspected to be counterfeit goods.[44] This would have a negative effect on access to and the making available of affordable medicines in Uganda.*

***South Africa***

*HIV infection is one of the main health challenges facing South Africa today. It is estimated that 5.6 million people were living with HIV in South Africa in 2009 more than double the number of people that were living with HIV in India, which has the second biggest HIV infected population in the world.* [45]

*Between 1998 and 2001, South Africa was embroiled in a highly publicized court case where close to 40 pharmaceutical companies had taken South Africa to court over its Medicines and Related Substances Act.*[46] *The main issue was Amendment 15(c) of the Medicines and Related Substances Act which allows local production of generics and TRIPS-compliant compulsory licensing and parallel imports of medicines in South Africa. This effectively allowed the government to override patent rights in the pharmaceutical sector on public health grounds and permit the use of parallel importing and compulsory licensing. The matter led to a legal action against the South African government by the drug companies, which argued that the new law conflicted with the South African constitution and contravened WTO patent rules. This is despite*

42 Ginamia, M. (2010).

43 Von Braun, J. and Munyi, P. (2010), pp. 238–253

44 Wasswa, H. (2008), p. 7640.

45 UNGASS. South Africa UNGASS Country Progress Report 2010.

46 Averting HIV and AIDS (n.d). *AIDS, drug prices and generic drugs* [online]. <http://www.avert.org/generic.htm> (Accessed 01 September 2010).

*two of the pharmaceutical companies abusing their dominant position by violating the domestic competition law by means of refusing to grant licenses for patents on essential AIDS medicine.[47] As a result of the legislation, the US placed South Africa on its Special 301 Watch List and filed a complaint against South Africa with the WTO. The case was eventually dropped by both the US and the drug companies due to intense pressure from the international community. This was a significant case as it brought access to medicines for poor countries into the public consciousness. The end of the lawsuit cleared the path for the Medicines Act to go into force, allowing importation of affordable medicines and increased use of quality generic drugs. Today, South Africa produces a significant number of generic drugs by importing generic APIs and formulating them locally. In a turnaround of events, now, several pharmaceutical companies have granted South African generic drug companies voluntary licenses and non-assert declarations to improve access to ARVs. That said, there remains a need to devise ways of procuring cheaper second-line drugs.*

### 2.3.2 Bilateral Agreements ('TRIPS-plus') and Access to Medicines

It has been argued that free trade agreements, bilateral investment treaties and economic partnership agreements, especially between a developing and developed country, are not the best option for a developing country and that multilateral negotiations and agreements are preferable.[48] Many African countries are pursuing trade and economic frameworks and agreements with developed countries in order to attain commercial benefits. This has led to a surge in bilateral agreements which are negotiated outside the WTO and therefore the auspices of the TRIPS Agreement.[49] These trade agreements are usually negotiated with little transparency or participation from the public, and often establish TRIPS-plus provisions. These provisions undermine the safeguards and flexibilities discussed earlier that developing countries sought to preserve under TRIPS.[50] Often developing countries have weaker economies, capacity and negotiating resources leading to a weaker bargaining position. Furthermore, in many cases, these free trade agreements call for even higher protection for medical technologies than is mandated by the TRIPS Agreement.[51] "TRIPS-plus" as this higher protection is called, is an informal term for the protection of intellectual property rights that goes beyond the requirements in the TRIPS Agreement. TRIPS-plus standards typically call for:

- **Patent term extension**. Patent lifespan that is longer than the 20-year duration provided in TRIPS. This is not usually a general extension, but applied in the case of regulatory delays or delays in the granting of the patent. An analysis of 24 HIV/AIDS

47 Reichman, J. (2009).

48 Third World Network (2009).

49 Raja, K. (2009).

50 3D Three (2004) [online]. Denmark and Italy Trade-related intellectual property rights, access to medicines and human rights. <http://www.3dthree.org/pdf_3D/3DCESCRDenmarkItalyBriefOct04en.pdf> (Accessed on 1 July 2011).

51 Raja, K. (2009).

drugs produced by 26 patent owners indicates that 11 patents received some extensions in the United States, including Celexa. [52]

- **Data exclusivity**: Data exclusivity prevents a producer of generic medicines from making use of the original clinical test data for a number of years. This forces the generics company not only to submit its own test data if it wishes to bring a medicine on the market but also to execute new studies, costing time and money.
- **Patent linkage with drug registration and approval**. To strengthen their monopoly, patent-owning medical technology companies could push medicine registration bodies to only register generic versions of medicines once the patent has expired. This would mean that a generic medicine imported or manufactured under compulsory license may not be registered until the patent has expired and therefore effectively when the compulsory license is no longer required.

**New enforcement mechanisms for IPRs**. These include criminal sanctions for infringements of intellectual property rights and seizure of goods suspected of infringing any intellectual property rights during importation, exportation or transit.[53] The additional restraints imposed by such free trade agreements impact on public health in several ways. First, the stronger intellectual property rights that are imposed under such agreements impact on the affordability of medicines by reducing the availability of more affordable generic brands in the market and promoting anti-competitive practices. Second, the extension on patent terms allow for monopoly pricing beyond the 20-year duration of the patent, keeping the prices of medicines artificially high if no measures are put in place to reduce them. Third, data exclusivity precludes generic companies from using originator-company data to prove the bioequivalence of a generic version for the period defined in the free trade agreement. The combined effect is that it delays generic competition and further inhibits availability.

### 2.4 Concluding Remarks

#### 2.4.1 Health Technology Research in Africa

The relationship between research and socio-economic development is well documented.[54] Research leads to the creation of knowledge and new technologies which are then translated into products, processes and services applied and utilised for social and economic gain. Emerging economies such as China, India, Malaysia, Singapore, South Korea and South Africa have been able to make significant advances as a consequence of increasing their research and development skills and capacities in a variety of science and technology disciplines.[55] Many African countries are excluded from this opportunity and struggle to harness R&D for the benefit of their economies.

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52 Bhat, V. N. (2005), pp. 109–122. Also see "Determination of Regulatory Review Period for Purposes of Patent Extension; Celexa, " Federal Register, February 25, 2002, (Volume 67, Number 37): pp. 8546-8547.

53 Khor, M. (2005).

54 WIPO. [Online] <http://www.wipo.int/patent-law/en/developments/economic.html> (Cited: July 28, 2010); Kettler, E. and Modi, R. (2001), pp. 742-747; Sihanya, B. (2002).

55 United Nations (2005); Science and Development Network (SciDev Net) (2005) [online]. <http://www.scidev.net/en/latin-america-and-caribbean/policy-briefs/how-governments-can-boost-business-r-d.html> (Accessed 28 July 2010).

Even though African institutions face low and declining investment in health research, many institutions have been able to use what little resources are available to them to develop high impact health innovations. The NEPAD paper on Science, Technology and Innovation for Public Health in Africa[56] offers suggestions on how Africa can tap into science, technology and innovation tools to address Africa's current huge burden of disease. Firstly, the paper suggests that Africa needs to show leadership in generating, developing and applying health innovations needed to address diseases unique to the continent. This includes a plan to address Africa's disease with locally manufactured drugs and diagnostics that are specific to the disease states and conditions that exist in Africa. Furthermore, Africa needs to set its own health research and innovation agenda in order to tackle the health challenges. To this end, there is a call for global funding mechanisms for public health, to go beyond the call of treating disease symptoms and focus on building capacity in health research and development. There is also a need to strengthen access to health systems information through improved and more effective communication. With fragile health research and health services infrastructure, it is necessary to create market incentives to support health innovation, product R&D and access to essential medicines.[57]

### 2.4.2 Uganda

While it is developing its IP laws, Uganda should be encouraged to include in its IP bill all the flexibilities and safeguards available in the TRIPS Agreement and Doha Declaration and discouraged from including provisions that go beyond the requirements of the TRIPS Agreement (termed "TRIPS-plus" provisions). The TRIPS flexibilities discussed should be adapted to Uganda's development needs and drafted in a way that ensures access to medicines and the fulfilment of Uganda's human rights obligations under the ICCPR.[58]

Where a policy mandate is spread across different national agencies as is the case with intellectual property, coordination and cross referencing is essential to avoid contradictory and therefore confusing policy. Such situations can cause tension between agencies responsible for enforcement and those reponsible for implementation and providing guidelines.

Given the low level of innovation output in Uganda, the IP policies need to have relevance on the ground rather than to remain theoretical frameworks that have little application to those for whom they have been created. Ideally, IP policy should provide clear guidance to researchers and industry, encourage innovation, trade and investment, promote technology transfer to benefit local manufacturers and to harness locally generated IP for social and economic development. Focus on these desired outcomes should be maintained.

Adequate human resource capacity and capability is needed for policy implementation; especially experts who are able to interpret and apply the policies correctly in sectors such as industry, the judiciary system, trade, enforcement and academia. There is a need to strengthen training and to build human resource capacity that will assist Uganda to achieve the objectives for embarking on its massive drive to modernise and align itself with international agreements to which it is party.

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[56] Kalua, F.A., Awotedu, A., Kamwanja, L.A. and Saka J.D.K. (eds) (2009).

[57] African Network for Drugs and Diagnostic Innovation (ANDi) (2008); Commission for Africa (2005).

[58] The ICCPR is the International Covenant on Civil and Political Rights, which Uganda has ratified, directly addresses basic human rights, and nations' obligations to defend these rights.

### 2.4.3 South Africa

South Africa has the capability to manufacture ARV generics for use locally and elsewhere in Africa. The challenge will be to ensure that the drugs manufactured are of high quality and do not cost more than those produced in countries like India and Brazil. South Africa needs to accelerate the development of a competitive generics manufacturing industry in order to accelerate access to HIV/AIDs drugs and health innovations.

While the scale of health research in South Africa remains small relative to developed countries, it is significant when compared to the rest of Africa. Health research into HIV/AIDS, malaria and TB is widespread within the country and important results to combat these diseases are being generated. There is a need, however, to encourage more North-South interactions within the African continent to fast track knowledge and technology transfer and contribute to improving other research facilities in Africa.

# CHAPTER 3 BACKGROUND TO ART-A

## 3.1 Introduction

This section outlines HIV epidemiology and treatment and the importance of laboratory-based monitoring of HIV treatment and HIV drug resistance (HIVDR) testing. It will explain the ART-A research consortium, its objectives and activities, the technology being developed, and identify the key intellectual property issues that need to be addressed to ensure that the knowledge generated as a result of the ART-A consortium research activities is freely available and can be effectively used in Africa. It will cover how this research plans to address IP issues so that the efforts of ART-A and resulting test methods can be effectively applied within the existing intellectual property environment in Africa to ensure that both the knowledge and technology creators and end users of the knowledge (doctors and patients) can benefit from the knowledge.

## 3.2 Relevance of HIV Epidemiology and Treatment

The relevance of the HIV epidemic and the importance of MDG 6 are highlighted by epidemiological estimates at the end of 2009 suggesting 33.3 million people globally were living with HIV, with 22.5 million or 67.5% of these people living in Sub-Saharan Africa.[59] It is now well recognised that antiretroviral (ARV) drug treatment is effective in both controlling HIV replication and preventing the development of AIDS.Whilst guidelines for when to begin ARV treatment differ slightly, the WHO (in guidelines updated in 2010) recommends that HIV-infected adults should start ARV therapy when a laboratory test shows a particular type of immune cell called CD4 has a cell count ≤350 cells per $mm^3$, and if CD4 testing not available, treatment should be started for those with WHO clinical stage 3 or 4 symptoms.[60] Using these criteria it has been estimated that by end of 2009 there were 14.6 million people in need of treatment globally and of these, 10.6 million were living in Sub-Saharan Africa.

A major target of MDG 6 by 2010, was to achieve universal access to treatment[61] and progress towards this target can be effectively measured by determining the proportion of individuals who meet the WHO criteria for treatment and have access to ARV drugs. Whilst universal treatment access has not yet been achieved, HIV treatment access has been scaled up massively, almost thirteen fold since 2003, and by the end of 2009 more than 5.25 million adults were receiving ARV treatment in low- and middle-income countries as compared to 3 million at the end of 2007.[62] At the end of 2009, 3.9 million patients receiving treatment were living in Sub-Saharan Africa translating to treatment coverage of 37% in this region.

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59 Unaids (2010). Global report on the global AIDS pandemic. <http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2010/20101123_globalreport_en.pdf> (Accessed on 1 July 2011).

60 World Health Organization (2010).

61 Millenium Development Goals.<http://www.undp.org/mdg/goal6.shtml> (Accessed on 1 July 2011).

62 World Health Organization (2010).

### 3.3 HIV Drug Resistance (HIVDR)

At the same time, the emergence of resistance to ARV drugs is a real and growing problem. Over time, the viruses that patients are infected with develop resistance to the ARV drugs that they are taking, making it likely that patients will require different and more expensive combinations of ARV drugs for effective treatment.[63] One recent study in the United Kingdom estimates that virological failure in patients is common by the eighth year of ARV treatment.[64] Unchecked HIV resistance creates the added problem that it limits future treatment options for patients.[65] This means if resistance is not identified early and patients are moved to different regimens then one can exhaust the drug treatment options available.[66] This has huge implications for publicly funded treatment programs that rely on standard treatment regimens with limited drug options and where ARV drug procurement is based on tenders.

If ARV treatment is not properly monitored, the risk of maintaining patients on failing regimens increases and patients may be prematurely and inappropriately switched to more expensive second line treatments based on suspicion rather than fact. Currently, the monitoring of effective HIV therapy relies on a combination of clinical indicators as well as available *in vitro* diagnostic tests, namely $CD_4$ count, HIV viral load (HIVVL) and actual HIVDR tests. Since a key goal of ARV therapy is to suppress HIV viral replication for as long as possible to below the limits of detection of commercially available HIV viral load assays[67] the development of drug resistance is best tracked, following initiation of ARV therapy, by measuring HIV viral load over time (at different intervals). Should an increase in viral load be detected (usually to above 1000 viral RNA copies/ml) then investigation into possible reasons for drug failure (drug adherence or drug resistance) should be initiated.

It is possible to test for specific HIVDR using laboratory tests, and a number of different methods can be used to determine HIVDR which include phenotypic and genotypic HIVDR assays.[68] The more practical method is the genotypic assay which involves determining the gene sequence of specific HIV genes in an infected patient and checking if such sequences are likely to confer resistance to particular HIV drugs.

The problem with implementing HIVDR tests, however, is that they are extremely expensive and require significant infrastructure both in terms of laboratory design, layout and equipment as well as highly skilled laboratory personnel to perform the assays. In fact, a single HIVDR test performed using commercially available assays can cost more than an entire year's supply of ARV drugs for a single patient.[69] To date, research and development

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63 Bansi, L., Smith, C., Phillips, A., Kirk, S., Geretti, A. M., Johnson, M., Mackie, N., Post, F., Gazzard, B., Dunn, D. & Sabin, C. 2011. The impact of HIV drug resistance testing on changes to treatment. *AIDS,* 25, pp. 603-610.

64 Cozzi-lepri, A., Dunn, D., Pillay, D., Sabin, C. A., Fearnhill, F. and Geretti, A. M. et al. (2010), pp. 1275-1285.

65 Deeks, S. G. (2003), pp. 2002-2011.

66 Kantor, R., Shafer, R. W., Follansbee, S., Taylor, J., Shilane, D., Hurley, L., Nguyen, D. P., Katzenstein, D. and Fessel, W. J. (2004), pp. 1503-1511.

67 Department of Health and Human Services(2009). Panel on Antiretroviral Guidelines for Adults and Adolescents.Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. pp. 1-161. <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf> (Accessed 03 January 2010).

68 Sebastian, J. and Faruki, H. (2004), pp. 115-125.

69 In 2005 the costs of antiretroviral drugs for treatment of an individual in South Africa was estimated at ZAR1, 167 per year and the cost of a single HIV drug resistance test at that time in a government lab was higher.

activities seeking low cost, reliable and scalable methods to measure viral load,[70] never mind the more complex HIVDR assays, have not been successful.

Due to these factors, the way in which treatment is monitored and HIVDR is actually detected differs widely around the world depending on resources available for testing. When comparing diagnostic monitoring guidelines in the resource rich or developed regions of the world (like the United States and Britain) with those of African countries (like South Africa and Uganda) and those recommended by the WHO for resource limited settings, large differences are observed.

The US Department of Human Health and Human Services HIV Treatment guidelines[71] recommend that genotypic HIVDR testing be conducted to guide therapy from the moment a patient enters care, to managing suboptimal virologic responses and when virologic failure occurs. Whereas the South African HIV Clinicians Society Treatment Guidelines recommend that treatment failure should be monitored by assessing HIV viral load and looking for the emergence of new clinical signs and symptoms,[72] with no mention of HIVDR testing. The WHO guidelines state that it *"does not recommend HIV drug resistance testing for individual patient management in settings where CD4 and HIV viral load tests are not yet available".*[73]

Because HIVDR testing is not routinely performed in the public sector anywhere in Africa and even the less costly HIV viral load assays are not done in many African countries, doctors are left to rely either on clinical signs to assess treatment effectiveness, or to utilise CD4 measurements to assess treatment failure.

CD4 measurements, however, have been shown to be unreliable in determining treatment failure or drug resistance in many studies.[74] So in the longer term, affordable technologies to monitor HIV treatment efficacy and associated drug resistance are required. This is the specific aim of the ART-A program.

### 3.4 The Affordable Drug Resistance Test for Africa (ART-A) Program

The program called ART-A (an acronym for Affordable Drug Resistance Test for Africa) was initiated by the Centre for Poverty Related Communicable Diseases (CPCD), Academic

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<http://www.journaids.org/index.php/essential_information/hivaids_treatment/_the_cost_of_treatment_in_south_africa/> (Accessed on 1 July 2011).

70 Bangsberg, D. R. 2008. A paradigm shift to prevent HIV drug resistance. *PLoS Med,* 5**,** p. 111.

71 Department of Health and Human Services (2009). Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. pp. 1-161. (Accessed 03 January 2010). <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>.

72 Southern African HIV Clinicians Society. Guidelines: antiretroviral therapy in adults (2008), p. 21. <http://sahivsoc.org/index.php?option=com_docman&task=doc_details&gid=40&Itemid=67> (Accessed on 1 July 2011).

73 World Health Organization (2010). Antiretroviral therapy for HIV infection in adults and adolescents: recommendations for a public health approach -2010 rev. <http://whqlibdoc.who.int/publications/2010/9789241599764_eng.pdf> (Accessed on 1 July 2011).

74 Hosseinipour, M. C., Van Oosterhout, J. J., Weigel, R., Phiri, S., Kamwendo, D., Parkin, N., Fiscus, S. A., Nelson, J. A., Eron, J. J. and Kumwenda, J. (2009), pp. 1127-1134; Reynolds, S. J., Nakigozi, G., Newell, K., Ndyanabo, A., Galiwongo, R., Boaz, I., Quinn, T. C., Gray, R., Wawer, M. and Serwadda, D. (2009), pp. 697-700.

Medical Centre, at the University of Amsterdam in 2006. ART-A is developing methods and protocols to specifically address the issue of making available reliable, scalable and affordable HIV treatment-monitoring tools and algorithms (including HIV-1 drug resistance testing protocols) that can be effectively and sustainably used by laboratories providing HIV testing services to clinics in Africa.[75] It is anticipated that this will provide more practical and affordable options to the current commercial assays for viral load and HIVDR testing. The long term view is to incorporate such testing into individual patient management in order to improve treatment management and hence HIV treatment outcome.

Funding for the ART-A project is administered through The Netherlands Foundation for the Advancement of Tropical Research, a non-profit research organisation which forms part of the Netherlands Organisation for Scientific Research (NWO/WOTRO). The latter organisation is responsible for receiving and distributing funding provided by the Netherlands Ministry of Education, Culture and Science and the Netherlands Ministry of Foreign Affairs.

ART-A involves the collaborative efforts of six entities in a public-private partnership (PPP) with partners from the developed and developing world. These entities are described below and their roles in the consortium further explained in Table 3.1:

1. **Centre for Poverty-related Communicable Diseases (CPCD**), Academic Medical Centre, University of Amsterdam – this centre is the main recipient of program funding and is involved in overall program oversight.
2. **PharmAccess Foundation**, Amsterdam – this is a Dutch not-for-profit organisation dedicated to strengthening health systems in Sub-Saharan Africa with the goal of improving access to quality basic healthcare including treatment of HIV.
3. **Wits Health Consortium (Pty) Ltd. (WHC)** – this is a wholly owned subsidiary of the University of the Witwatersrand, Johannesburg (South Africa). It represents the research interests of the the University's Faculty of Health Sciences and has a division called Contract Lab Services that provides technical training and support services to laboratories in Africa.
4. **University Medical Centre Utrecht (UMCU)** – this is one of the largest public healthcare institutions in the Netherlands and has extensive knowledge on ARV therapy and HIVDR. UMCU has a WHO accredited drug resistance testing laboratory.
5. **Centre de Recherché Public de la Santé (CRP-Santé)** – this is a public research institute based in Luxembourg that conducts basic, pre-clinical and clinical biomedical research to improve treatment strategies and public healthcare for major medical conditions.
6. **Virco BVBA** – a research-based biotechnology company established in 1995 that was subsequently acquired by Johnson and Johnson (New Jersey, US) in 2001. The company provides commercial HIV and Hepatitis C virus (HCV) drug resistance assays and develops resistance testing tools using technologies in molecular biology, virology, genomics, robotics and electronic data processing to improve the diagnosis and management of infectious diseases.

[75] Affordable resistance test for Africa [online]. <www.arta-africa.org> (Accessed on 1 July 2011).

**Table 3.1** ***Summary of ART-A consortium members showing type of entity, location, role in the consortium and website address***

| Consortium Member Legal Entity | Type | Location | Role in Consortium | Website |
|---|---|---|---|---|
| University of Amsterdam (Centre for Poverty-related Communicable Diseases, Acad. Med. Centre) | University | Amsterdam, The Netherlands | Main recipient of funding and program oversight | www.amc-cpcd.org |
| PharmAccess Foundation | Not-for-profit organisation | Amsterdam, The Netherlands | Implementing agency and project management for the ART-A program | www.pharmaccess.org |
| Wits Health Consortium (Pty) Ltd. | University-owned subsidiary company | Johannesburg, South Africa | Development of convenient sample collection device and extraction protocol to facilitate HIVDR testing and also facilitate technology transfer and training | www.witshealth.co.za |
| University Medical Center, Utrecht | Public healthcare institution | Utrecht, The Netherlands | Development of affordable and easy to use gene amplification and analysis methods for HIVDR testing | www.umcutrecht.nl/research |
| Centre de Recherche Public de la Santé | Public research institution | Luxembourg | Development of affordable and easy to use software for HIVDR sequence analysis | www.crp-sante.lu |
| Virco BVBA | Private company owned by a public company (J&J) | Belgium | Assisting in amplification and analysis methods development and optimization Implementation, optimization and interpretation of resistant gene sequence methodology | www.vircolab.com |

The strength of this consortium is that it employs the unique expertise and infrastructures of the different public and private organisations based in the developed world (the Netherlands, Belgium, and Luxembourg) and developing world (South Africa) to design and implement practical solutions for HIV treatment monitoring and drug resistance testing to support effective HIV treatment in Africa. ART-A is therefore a good example of a public-private partnership (PPP) where both public and private entities share expertise and resources in developing genetic *in vitro* diagnostic tools, namely an HIV viral load monitoring and a genotypic HIVDR test,that will have direct impact on the management of patients in Africa on ARV therapy. The use of genotypic HIVDR testing can be considered as an excellent example of personalised medicine (also called companion diagnostics or theranostics) where results from these tests generate reports which then guide treating doctors in selecting the correct combination of drugs for effective treatment.

## 3.5 Technologies in Development by ART-A and their Competitive Advantages

Measuring HIV viral load and determining HIV genotypic resistance generally involves the following steps:

1. Collection of a blood sample from patient
2. Extracting viral nucleic acids from the patient sample
3. Amplifying the nucleic acid from relevant gene regions of a virus to either quantify the viral load or to provide sufficient DNA template for sequencing
4. Sequencing the polymerase and protease regions of amplified DNA to identify gene sequences representative of the viral population in the patients. These sequences obtained are then compared with other known drug-resistant sequences to determine the presence of mutations that are known to cause drug resistance.

A number of commercial assays for HIV VL and genotypic HIVDR testing that are available on the market are summarised in Table 3.2 and 3.3 respectively. The table shows technologies that are used in these assays and that have intellectual property rights associated with them (i.e., are patented or subject to license agreements). The ART-A research program is developing and validating improved "home-brew"[76] methods similar to existing commercial assays. The difference with the ART-A technology being developed is that the assays can be performed more cost effectively and operate on "generic" or "open" nucleic acid extraction, amplification and sequencing platforms.

[76] "Home-brew" methods are generally regarded as those that are performed in laboratories using methods developed by the laboratory (or derived from a published method) where individual assay components are sourced from different suppliers and the assays run according to a protocol rather than through the purchase of a standardised commercial kit. It has the advantage often of being cheaper but can lack the benefits of easy standardisation between laboratories.

**Table 3.2** ***Commercial HIV Viral Load Assays***

| Brand Name | Manu-facturer | Technologies Incorporated[77] | Limitations |
|---|---|---|---|
| Abbott RealTi*me HIV-1* | Abbott Molecular Inc, Illinois USA | ❑ PCR (Real-time)<br>❑ Fluoresent probe detection<br>❑ Armored RNA | ❑ Closed system (requires Abbott instrument systems)<br>❑ Difficult to optimise platform to test volume requirements of individual laboratory and technology tends to only support high throughput laboratories.<br>❑ High cost per test (high volumes required to negotiate reduced cost) |
| Versant Human Immunodeficiency Virus Type 1 (HIV-1) RNA bDNA v3.0 | Siemens Healthcare Diagnostics | ❑ Instrument for monitoring nucleic acid amplification<br>❑ 5′ exonuclease methods | ❑ Closed system (requires Siemens instrument systems)<br>❑ Difficult to optimise platform to test volume requirements of individual laboratory<br>❑ High cost per test (high volumes required to reduce cost) |
| COBAS® AmpliPrep/COBAS® TaqMan®HIV-1 Test, version 2.0 | Roche Molecular Systems Inc., NJ, USA | ❑ Armoured RNA<br>❑ Paramagnetic particles<br>❑ Cyanine dyes<br>❑ Other technologies not specified | ❑ Closed system (requires Roche COBAS instrument systems)<br>❑ Difficult to optimise platform to test volume requirements of individual laboratory<br>❑ High cost per test (high volumes required to reduce cost) |
| NucliSens HIV-1 EasyQ v2.0 | Biomerieux | ❑ Nucleic acid, isolation, amplification and detection technologies<br>❑ Molecular Beacons (DNA hybridisation probes that fluoresce on | ❑ Closed system (requires Biomerieux instrument systems)<br>❑ Difficult to optimise platform to test volume requirements of individual laboratory<br>❑ High cost per test (high volumes required to reduce cost) |

[77] All information on technologies incorporated that have IPR attached to them was derived from information provided in the package inserts of commercial assays. Most package inserts list patents and licenses provided to technologies included but it is possible that there are other technologies or methods where related IPR is not listed.

**Table 3.3** ***Commercial Genotypic HIV Drug Resistance Assays and Technologies Incorporated with IPR***

| Brand Name | Manu-facturer | Technologies Incorporated | Limitations[78] |
|---|---|---|---|
| ViroSeq™ HIV-1 Genotyping System | Celera Corporation | ❑ DNA sequencing methods<br>❑ Unique primer sequences<br>❑ One tube PCR<br>❑ PCR contamination control methods | ❑ Highest cost method<br>❑ Performance on some HIV subtypes poor<br>❑ Labour intensive and complex procedures<br>❑ Reliability of supply of equipment and reagents variable in different countries<br>❑ Semi-open system – large capital equipment costs<br>❑ Sequence analysis software system specific<br>❑ Moderate biohazard waste generated |
| TRUGENE® HIV-1 Genotyping Kit | Siemens Healthcare Diagnostics | ❑ Nucleic Acid Amplification<br>❑ DNA Sequencing processes (including automated, single tube and bi-directional methods)<br>❑ Fluorescent labelling of primers<br>❑ Electrophoresis microgels<br>❑ DNA natural abundance sample evaluation methods<br>❑ Cyanine dyes<br>❑ Reverse transcriptase lacking RNase H activity | ❑ High cost method<br>❑ Performance on some HIV subtypes poor<br>❑ Closed system – medium capital equipment costs<br>❑ Highly labour intensive and complex procedures<br>❑ Sequence analysis software system specific<br>❑ Reliability of supply of equipment and reagents variable in different countries<br>❑ High volume biohazard waste generated |

[78] Modified from HIV Drug resistance training. Module 5: Sequencing procedures: Commercial and In-house.) <http://www.who.int/hiv/pub/drugresistance/HIVDR_Mod_5_Sequencing_Procedures.ppt> (Accessed 07 November 2010).

New knowledge, and as a result potential intellectual property, is being developed by the ART-A consortium covering some of the steps described for HIV drug resistance monitoring including:

1. A **simplified** patient sample collection using blood dried onto paper (dried blood spots) which will facilitate affordable sample transport to laboratories for testing.
2. **Optimised** methods for extracting and purifying the genetic material from such samples and amplifying the genetic material to detectable levels both for quantification and providing material suitable for sequencing
3. **Optimising** more affordable and reliable sequencing techniques as well as gene sequence, alignment and base calling software to accurately predict the correct and relevant HIV gene sequences in infected patients. The resulting good quality nucleic acid sequences can then be analyzed in public domain or other databases to identify specific drug resistance mutations and advise on suitable drug combinations for effective therapy.

As a result of the inherent sequence diversity of HIV-1 isolates, many of the commercial HIVDR assays do not always accurately amplify and therefore correctly detect all known HIV-1 subtypes or related isolates. This effect compromises the reliability of the drug resistance data.[79] The nucleic acid sequence of primers, their design and validation is therefore a critical component of such assays to ensure that all subtypes are accurately measured and is therefore a major feature of ART-A research and development activities. In addition to developing assays,the ART-A consortium is also providing laboratories with training in the technical methods as well as facilitating and advising on laboratory design, layout and the procurement of reagents to allow for the use of such technologies in countries in Africa.

### 3.6 Technology Users and Beneficiaries

The development of HIVDR is considered to be inevitable in populations taking ARV therapy.[80] The ultimate aim of ARV treatment is to prevent HIV-infected patients from developing AIDS by keeping viral replication maximally suppressed. Therefore cost effective treatment monitoring tools are required to ensure that treatment is effective and that the best drug combinations are used. As already discussed, whilst monitoring HIV VL and HIVDR testing is the standard of care in the developed world, both are currently lacking in most of Africa.

ART-A technology will have a broad number of direct users located at healthcare facilities in Sub-Saharan African countries (Table 3.4) ranging from:

- Basic clinics in remote rural areas that benefit from dry blood spot collection methods
- Intermediate level clinics that will be enabled to perform viral load assays
- Highest level (tertiary) referral clinics and laboratories that will be able to conduct HIVDR testing for individual patients as well as providing information on drug resistance in the treated population

[79] Maes, B., Schrooten, Y., Snoeck, J., Derdelinckx, I., Van Ranst, M., Vandamme, A. M. and Van Laethem, K. (2004), pp. 45-49.

[80] Jordan, M. R., Bennett, D. E., Bertagnolio, S., Gilks, C. F. and Sutherland, D. (2008), pp. 15-23.

- Doctors who will use laboratory information to decide when to change ARV drug combinations and to select the most effective regimens (to the benefit of patients on lifelong ARV therapy).

**Table 3.4** ***Description of Users/Beneficiaries of ART-A Technology and Associated Benefits***

| Technology Component | Description of User/ Beneficiary | Benefits of technology |
|---|---|---|
| Dried Blood Spot Sample Collection and Transport System | Nurse, phlebotomist, laboratory technician or doctor | ❑ No dedicated refrigeration or storage facilities required (reduced storage space)<br>❑ No time constraints to get sample to laboratory – reduced courier costs<br>❑ Easy transportation of sample to lab - reduced biohazard and courier costs<br>❑ Overall reduced operational costs |
| | Primary, secondary and tertiary level public and private sector laboratories | ❑ Reduced costs of storage and shipping<br>❑ No repeat sample collection required due to sample stability and sample shelf life and a number of blood spots are collected at once to allow for repeat testing if necessary<br>❑ Easy sample storage, batching of testing, ideal for surveillance surveys |
| Viral Load Assay | Secondary and tertiary level public and private sector laboratories | ❑ Can be run on open platforms and with different reagent suppliers thereby increasing the number of labs that can use assay and improving purchasing power and reliability of supplies<br>❑ Assay can be tailor-made to small and larger test volume laboratories<br>❑ Reduced cost per test as compared to commercial assays<br>❑ Reliable amplification and detection of all HIV-1 subtypes |
| HIV DR Assay | Tertiary level public and private laboratories | ❑ Open system so can use existing or different capital equipment that has multiple uses<br>❑ Significantly reduced cost per test as compared to commercial assays<br>❑ Allows for standardization and data reliability<br>❑ Reliable amplification/detection of subtypes circulating in Sub-Saharan Africa |
| Combined Technologies for HIV ARV Treatment Monitoring | Governments, funding agencies | ❑ Reduced ARV program costs<br>❑ Improved surveillance and tracking of efficacy of ARV treatments programs<br>❑ Appropriate drug usage and timing of treatment change<br>❑ Reduced HIV drug resistance in treated population |

Both national governments and organisations that provide significant funding for ARV treatment programs like the Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM)[81] and the US President's Emergency Plan For AIDS Relief (PEPFAR)[82] need ways to assess the effectiveness and impact of treatment programs.[83] One objective measure of treatment effectiveness at a particular treatment clinic is to investigate the incidence and prevalence[84] of HIVDR in patients being treated at that clinic. By using ART-A tools to sample HIVDR in patients one can measure HIVDR at a population or clinic level and resulting data can be incorporated into HIVDR surveillance activities which are important to ensure optimal use of ARV therapy.[85] In 2000, the WHO developed a strategy to monitor HIVDR which includes standardized HIVDR monitoring surveys in specific national sites.[86] They expanded this program in 2009 to include a HIVDR laboratory training package along the lines of ART-A (including protocols for analyzing dried blood spots) and this information is publicly available.[87] The ART-A methodology, as distinct from the WHO HIV drug resistance testing methodology, is focused on compatibility with a wider range of generic reagents, software and instrument platforms found in Africa and has improved subtype coverage and sensitivity, with focus on compatibility with first line antriretorviral drug regimens used in Africa.The WHO does not address any of the potential intellectual property issues in their suggested HIVDR testing protocols. It is therefore envisaged that the ART-A intellectual property research described here will also inform the application of WHO protocols for HIVDR resistance in terms of intellectual property rights given that the technologies used in performing the assays are similar.

### 3.7 Intellectual Property Challenges Faced by the Consortium

Due to the inherent complexity of the consortium and the technologies being developed, IP issues represent a significant challenge to ART-A. Intellectual property is being developed by different entities located in different countries with different legal systems and by entities with potentially different mandates (public health or not-for–profit interests vs. private or for-profit interests), and in addition the users of IP will be located in different countries. Therefore, the identification, ownership, protection and utilisation of intellectual property need to be considered.

The funders of the ART-A consortium, the Netherlands Organisation for Scientific Research (NWO), have specifically acknowledged the importance of intellectual property rights and have provided for specific requirements in terms of: confidentiality; ownership of knowledge by the respective participants; protection of knowledge especially where knowledge is capable of commercial application; access rights or licenses, and use of rights for

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81 The Global Fund [online]. <www.theglobalfund.org> (Accessed on 1 July 2011).

82 The United States President's Emergency plan for AIDS relief. Smart Investments for women and families: PEPFAR and PMTCT [online]. <www.pepfar.org> (Accessed on 1 July 2011).

83 Willyard, C. (2010), p. 9.

84 HIV drug resistance incidence refers to the rate of new drug resistance mutations arising in an HIV-infected patient group over time, whereas prevalence of drug resistance is the percentage of drug resistance mutations in the patient group at a particular point in time.

85 Buckton, A. J. (2008), pp. 653-658.

86 Jordan, M. R., Bennett, D. E., Bertagnolio, S., Gilks, C. F. and Sutherland, D. (2008), pp. 15-23.

87 <http://www.who.int/hiv/pub/drugresistance/lab_training/en/index.html> (Accessed 7 November 2010).

the new knowledge and pre-existing know-how of consortium members of the project. Their objective is to ensure that the knowledge generated is freely available for use in Africa.

Given the number of different partners involved, their locations, differing levels of input and background intellectual property, and their different roles in and contribution to the generation of new intellectual property, the management of intellectual property rights is by no means trivial. As a result, the consortium members identified the need to ensure that intellectual property arising from the collaborative research efforts could be effectively identified and ownership determined.Where necessary, intellectual property should be protected and ultimately managed to ensure that the methods developed can be effectively accessed and used in Africa without intellectual property-related restrictions.

In addition, it is advisable that the consortium ensures that the technologies developed by ART-A could be licensed or transfered to commercial partners in future. This could help to facilitate competition in the *in vitro* genotypic HIVDR testing market which is currently dominated by two players, namely Celera's Viroseq HIV-1 Genotyping System and the Siemens Healthcare Diagnostics TRUGENE® HIV-1 Genotyping Kit for Drug Resistance.

The intellectual property arrangements of the consortium need to be structured in such a way as to ensure that there is access to rights and so that methods will be widely used to ensure competition and widespread, more affordable access to HIVDR tests. Any impediments to this as well as potential areas of conflict or lack of clarity in IP arrangements need to be clarified and addressed.

### 3.8 Freedom to Operate and Gene Patents

In addition to the inherent intellectual property issues within the consortium around access rights to knowledge generated there is the added factor of needing to determine freedom to operate with respect to registered intellectual property by outside or third parties. In the case of patents in genetic testing, they are generally categorised into two types, either technology-specific patents or diagnosis-specific patents.[88] The technology patents cover the technologies to generate the genetic information such as nucleic acid extraction, amplification and sequencing, as well as computational tools for analysis of the genes. The diagnosis-specific patents cover the actual gene sequences that are important for a specific disease or that, in this case, would confer a specific type of drug resistance.

In the case of HIVDR testing, the techniques utilised to identify drug resistance cover both these types and therefore a careful analysis of patents in the field is required. At least 14 patents were identified by researchers in 2006 that looked specifically at patents covering computational methods for predicting HIV resistance.[89] There already has been a high-profile patent dispute between a European biotech company called Advanced Biological Laboratories (ABL) and Stanford University around infringement of ABL's bioinformatics patents by Stanford's free accessible online HIV Drug Resistance Database.[90] This dispute was settled, but it highlights the need for awareness and knowledge of the potential for infringements in this field that could impact on ART-A.[91] For these reasons, we will also

[88] Vlassak, K. and Schuller, K. (2007), p. 104.

[89] Carvajal-Rodriguez, A. (2007), pp. 63-68.

[90] Cohen, J. (2009), pp. 1156-1157.

[91] Butkus, B. (2009).

explore in some detail background IP and possible infringements that need to be considered with respect to technologies developed by ART-A.

Despite this, it seems that most of the patent disputes or potential for dispute in the HIVDR testing field are centered on technology-specific patents rather than diagnosis-specific patents. In fact, most gene sequences or viral mutations that are shown to confer particular HIVDR profiles, are not patented but are found either in public domain databases (e.g., the Stanford University HIV Drug Resistance Database[92]) or held as confidential databases by private companies in the field that have invested in building these databases over time (e.g., Virco BVBA).

[92] Liu, T.F. and Shafer, R.W. (2006).

# CHAPTER 4 CONSORTIUM IP ARRANGEMENTS

## 4.1 Introduction

Of critical importance in the establishment and maintenance of a consortium like ART-A is ensuring that the agreed IP arrangements are understood by all the parties and that they provide workable options for ownership, protection, access and transfer of the technology being developed.

Even simple issues can lead to difficulties if they are not properly defined, like for example: deciding on authorship and attribution for publications; timing of publications; determing who will own background and foreground IP[93]; who will be able to use it; and how costs for patenting will be shared.

The role of contractual agreements that define consensus reached between collaborative parties has been identified as a good means to achieve access and use of intellectual property.[94] It is therefore important that the contracts governing the ART-A consortium IP do not contribute to limitations in access of technology that could be imposed especially by patent law. IP arrangements between consortium members should be unambiguous to avoid potential conflicts or misunderstandings between consortium members, but at the same time flexible, to allow for options for licensing and transfer of intellectual property rights between consortium members and to other outside parties. Ensuring that a contractual environment exists between consortium members that can be employed in future to facilitate wide access to the developed technology is therefore important.

In addition, it is also important that intellectual property policies or research codes of the different participating organisations are also understood and differing objectives or goals are identified to see how they could also affect future consortium negotiations with respect to publications, ownership and licensing for research or commercial use. The role of institutional technology transfer offices (TTOs) have been identified as crucial in IP management in developing countries,[95] and since they play an important role in this consortium we also include here a review of institutional policies and research codes to identify gaps or conflicts. This will help to advise the options available for IP protection that could be considered by ART-A, to be discussed in Chapter 5.

This is not intended as a legal review but seeks to identify the main intellectual property issues in consortium agreements or institutional policies that may limit the effectiveness of the consortium in achieving its goals. It is important to realise that we are seeking to identify factors that would impede the overall aim of the consortium that intends to ensure the widest access and usage of the ART-A developed technologies in Africa.[96]

Our intention is to create awareness for other groups who are establishing research consortia with similar objectives, to help them avoid or minimise similar gaps or weaknesses.This is a different approach from commercial or for-profit entities that could be

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93 Foreground IP is generally regarded as IP that arises as a result of the project research and development activities, and background IP is the IP that existed before the project research and development activities started.

94 Overwalle, G. Van (ed) (2009).

95 Wolson R. (2007).

96 A stated goal in the ART-A funding agreement with NWO.

looking to create very strong, even blocking intellectual property positions. It has been suggested that having a technology platform with a blocking patent to one's technology is one of the critical requirements for success of start-up biotechnology companies seeking venture capital.[97] Although that would apply more to therapeutics, which have high costs of development, than diagnostics, where it has been argued that due to the lower costs of development, a gene patent incentive may not be necessary.[98]

### 4.2 Summary of Consortium Agreements

A summary of all contractual agreements concluded by the consortium is shown in Table 4.1. Each of these agreements are considered and discussed briefly below with respect to IP issues. The two main agreements that govern IP in the consortium are the Consortium Agreement and the NACCAP[99] Grant Terms and Conditions.[100] These are analyzed in more detail in Section 4.2. Figure 4.1 shows pictorially the relationship of the consortium funder (NWO) to all consortium members and the key agreements governing the consortium.

97 Pearson, H. (2009), pp. 22-24.

98 Triffett, D. (2010), pp. 800-806.

99 NACCAP – the Netherlands-African partnership for capacity development and clinical interventions against poverty-related diseases.

100 A full copy of the Terms and Conditions applying to NACCAP grants, second call (July 2006) is available at <http://www.nwo.nl/files.nsf/.../NACCAP_Terms_and_conditions_2nd_call.pdf>.

**Table 4.1:** ***List of all agreements concluded between ART-A consortium showing dates of signature to highlight sequence of agreements***

| Agreement Type | Signatory Date |
|---|---|
| Draft Terms of Consortium Agreement (Non-binding Proposal) | September 2006 |
| CDA all Consortium members | Early September 2006 |
| Letter to confirm that if grant was awarded to CPCD that PharmAccess would be sole implementing agency | Late September 2006 |
| Initial Grant Award Letter from NWO to CPCD | January 2007 |
| Consortium Agreement between all Consortium members | March 2007 |
| Grant Award Letter with terms and conditions attached | November 2007 |
| Collaboration Agreement between PharmAccess and UMCU | March 2008 |
| Collaboration Agreement between PharmAccess and CRP-Santé | April 2008 |
| Collaboration Agreement between PharmAccess and Virco BVBA | June 2008 |
| Collaboration Agreement between PharmAccess and WHC trading as Contract Lab Services (CLS) | June 2008 |
| Collaboration Agreement between PharmAccess and WHC trading as HIV Resistance Syndicate (HRS) | July 2008 |
| Employment Agreements between WHC and PhD students | August 2008 |
| MTA Virco BVBA and WHC governing materials that were transferred from Virco BVBA to WHC | March 2009 |
| MTA Virco BVBA and UMCU governing materials that were transferred from Virco to UMCU | October 2009 |
| MOU between JCRC[101] and PharmAccess to allow JCRC and PharmAccess to evaluate ART-A developed HIV drug resistance protocols in JCRC laboratories in Uganda | February 2010 |

[101] The Joint Clinical Research Centre (JCRC) is located in Kampala, Uganda. This non-profit limited liability company was founded in 1991 as a partnership between the Ugandan Ministries of Health, Education and Defense. It has a network of laboratories that provide HIV testing services to support ARV therapy in the region.

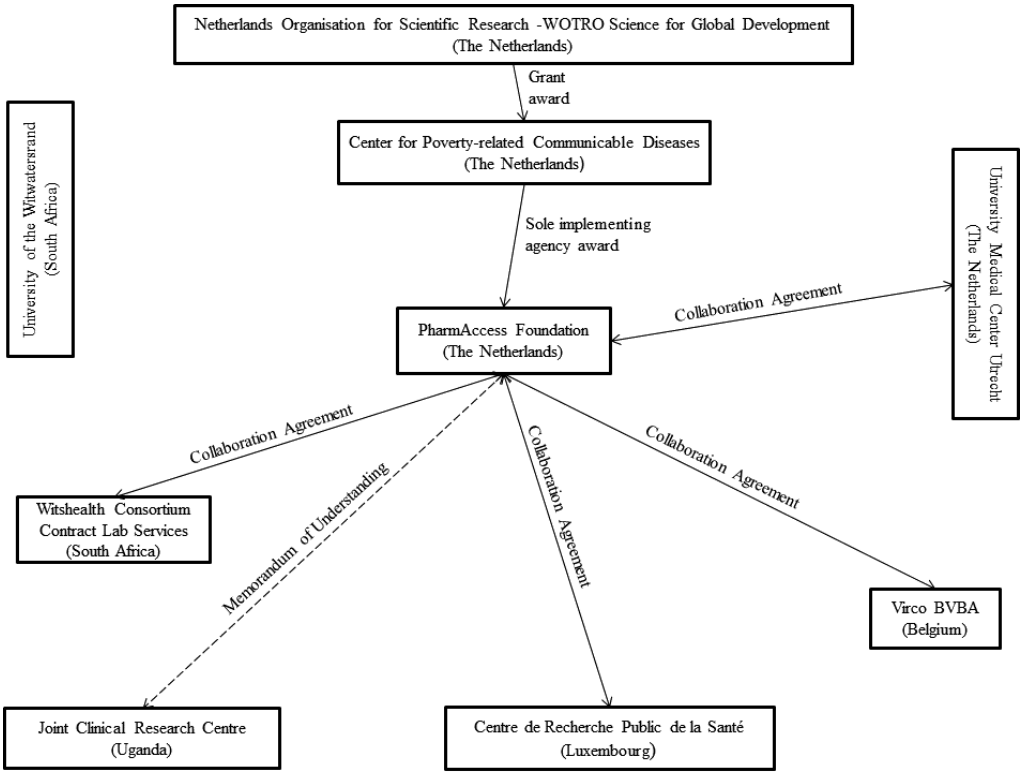


**Fig 4.1** ***Schematic diagram showing contractual arrangements between consortium members as defined by agreements concluded between consortium members.***

### 4.3 Initial Draft Terms of Consortium Agreement – Non-Binding Proposal

In September 2006, the members of the ART-A consortium concluded a non-binding agreement prior to the submission of their grant proposal to NWO to ensure all parties were aligned in terms of their expectations and objectives. If the grant was awarded it was intended that a legally binding consortium agreement would be established before proceeding with research activities. At this pre-grant stage, the non-binding agreement outlined that all consortium partners would grant (non-exclusive royalty free) access to the consortium of any background intellectual property rights that would be required for advancement of the program, provided that the granting partner agrees that the background IP is required for the advancement of the program. In addition, partners would need to explicitly indicate in advance the background intellectual property they do not wish to bring into the consortium. This was not done and consortium members did not provide descriptions of their background intellectual property, nor did they describe any IP that they did not wish to bring into the consortium.

### 4.4 Confidential Disclosure Agreement

A confidential disclosure agreement was entered into by consortium members to ensure that information shared in submission of the funding proposal was treated as confidential. This was a standard agreement and no potential conflicts were identified. However, when one maps all the parties to the Confidential Disclosure Agreement (CDA) (Fig 4.2), it can clearly be seen that the Center for Poverty Related Communicable Diseases (CPCD) was not included in the CDA but should have been a party to this agreement. CPCD was therefore not at this stage bound to confidentiality despite being the organisation that was going to submit the grant proposal to NWO. It proved not to be critical as the grant had not yet been awarded and no new confidential information or knowledge was generated prior to the award.[102] But it does demonstrate the importance of ensuring that all legal entities are party to all agreements at all times and highlights a role that institutional TTOs can play in reviewing and mapping agreements.

[102] It was also mitigated by the fact that the final agreement governing the grant included provisions for confidentiality.

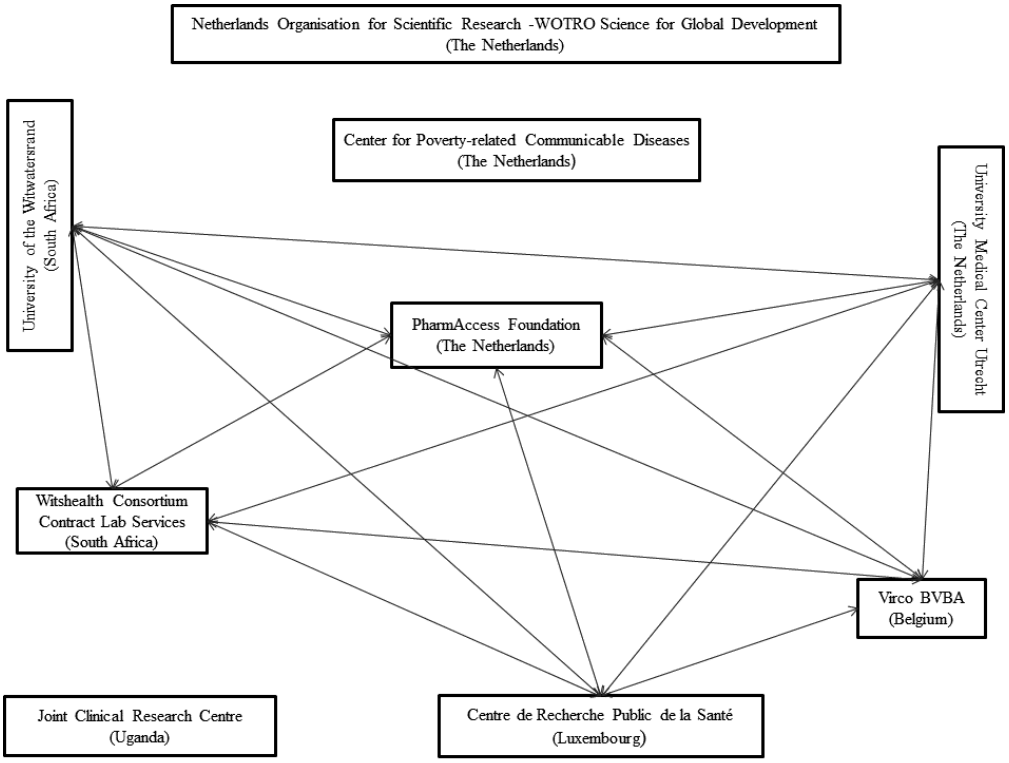


**Fig 4.2** ***Schematic diagram showing all parties that are included the pre-grant CDA***

### 4.5 Consortium Agreement between all Parties

Following the award of the NACCAP research and development grant to the ART-A consortium by the NWO in January 2007, the consortium was required to enter into a legally binding Consortium Agreement.[103] This served as the master agreement required to be in place prior to disbursement of the grant funds to the consortium; it deals extensively with intellectual property. This agreement defined background and foreground IP and states clearly that funding of the program aims to ensure that "the people of developing countries have easy and affordable access to the results produced by the activities performed by the parties".[104]

In terms of program governance, the ART-A program established a steering committee consisting of one authorised representative from each party under chairmanship of the CPCD member. It was this project steering committee that was responsible for overall management and performance of the ART-A program. Decisions are adopted unanimously or by a voted majority (with at least 6 members represented and each party having a single vote).

#### 4.5.1 NACCAP Grant Terms and Conditions

Following the finalisation of the Consortium Agreement, NWO advised the consortium that the Terms and Conditions Applying to NACCAP Grants, Second Call[105] "will prevail over the conditions you stated in your Consortium Agreement".[106] This meant in effect that consortium members had to examine whether terms and conditions differed between the Consortium Agreement and the funders' Terms and Conditions Applying to NACCAP Grants.[107]

### 4.6 Collaboration Agreements

In terms of the consortium research grant awarded by NWO to the CPCD, the PharmAccess Foundation was appointed as the research program's sole implementing agency to manage the research program, administer all payments to parties and co-ordinate the program's reporting requirements. As a result, PharmAccess then entered into individual Collaboration Agreements with each consortium member to define and govern the specific deliverables, budgets, payments and reporting requirements of each consortium member.[108]

All consortium members signed separate but similar agreements. There were no clauses dealing directly with IP, however each of these Collaboration Agreements stated that "this agreement will be subject to conditions imposed on the grant by NWO/WOTRO described in the 'Terms and conditions applying to NACCAP grants, second call'". Despite the

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103 As described in the NWO award letter to CPCD in January 2007.

104 Article 6 of ART-A consortium agreement.

105 <http://www.nwo.nl/files.nsf/.../NACCAP_Terms_and_conditions_2nd_call.pdf> (Accessed on 1 July 2011).

106 As described in the NWO grant award letter to CPCD in November 2007.

107 The NWO grant Terms and Conditions of NACCAP Grants, Second Call. (Accessed 02 December 2010). <http://www.nwo.nl/files.nsf/.../NACCAP_Terms_and_conditions_2nd_call.pdf>.

108 Steinbock, M. B. (eds) (2007).

NACCAP terms and conditions containing clasues around IP, the lack of clauses dealing with IP in the consortium agreements is a major issue. As an example, it is useful to refer to the high-profile dispute between Stanford University and Roche over ownership of patents for the PCR based measurement of HIV viral load (Box III-5). It highlights how the issue of owership of patents can be a major issue if not properly defined and managed.

**Box III-5: Roche and Stanford University Dispute over Ownership of Patents for PCR-based Measurement of HIV Viral Load.**

*In 2005, Stanford University sued Roche Molecular Systems for infringement of three patents it had filed relating to methods for PCR-based measurement of HIV viral load.*[109] *Following 4 years of litigation and a district court decision in May 2008, a final US Court of Appeals for the Federal Circuit decision in September 2009 determined that Stanford did not have the standing to sue Roche because it did not own the patents under infringement dispute (as Roche also had an ownership interest in these patents). It all came down to the fact that one of Stanford's researchers who had worked at a company called Cetus on PCR methods had signed a Visitors Confidentiality Agreement (VCA) that stated he assigned all rights to ideas, inventions and any improvements to Cetus. Roche subsequently purchased Cetus's PCR business including the agreements with Stanford and its researchers.This researcher had in fact also prior to signing the VCA with Cetus signed a Copyright and Patent Agreement (CPA) that required the researcher to agree to assign his rights to the University. But because this researcher was acting in his personal capacity as a consultant to Cetus and had signed his rights to Cetus, it was not possible for Stanford to establish that it possessed this researcher's interests in the three patents. As a result, Stanford lacked the "standing to assert its claims of infringement against Roche".*[110] *The complete ruling is decribed in detail in the Biotechnology Law Report of December 2009,*[111] *and serves to highlight potential IP ownership issues that can arise when researchers are involved in research, and binding agreements that involve IP assignment, with more than one organisation or legal entity. Interestingly, given the high financial stakes in this case and potential implications for the US Bayh-Doyle Act, the US Supreme Court agreed to review and rule on the case by June 2011 under request of top research universities.*[112] *On 6 June 2011 the US Supreme Court ruled that Stanford and Roche must share rights to the the patents and this effectictively dismissed Stanford's suit against Roche. The Court upheld the ruling of the Federal Court of Appeals decision in 2009, determining that the Stanford researcher had transferred rights to Cetus, and therefore to Roche, and thus Roche was a co-owner of the disputed patents with Stanford.*[113]

109 Biotechnology Law Report (December 2009) [online] Board of Trustees of the Leland Stanford Junior University and Thomas Merigan and Mark Holodniy v. Roche Molecular Systems, Inc. et al. <http://www.liebertonline.com/doi/pdf/10.1089/blr.2009.9890> (Accessed on 1 July 2011).

110 Ibid.

111 Ibid.

112 The National Law Journal (November 2010) [online]. Court will take up university patent fight. <http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202474248200&hbxlogin=1#> (Accessed on 1 July 2011).

113 The National Law Journal (June 2011) [online]. High court hands victory to Roche in case over inventors' rights.<http://www.law.com/jsp/nlj/PubArticleNLJ.jsp?id=1202496317099&slreturn=1&hbxlogin=1> (Accessed on 1 July 2011).

The Collaboration Agreements also stated that the agreement would "be subject to conditions stated in the 'Consortium Agreement'". So, as already mentioned, differences in terms and conditions applying to IP would need to be identified between the Consortium Agreement and the Collaboration Agreements (see Section 4.8).

All Collaboration Agreements included a clause on Governing Law and Jurisdiction which stated that the agreement would be governed by and construed in accordance with the Laws of the Netherlands and that disputes shall be exclusively settled by the competent court in Amsterdam, the Netherlands. This could potentially pose problems for non-Dutch entities in terms of resolving issues through legal channels, as they would have to be conducted in the Netherlands.

### 4.7 Other Agreements

The other agreements concluded by the consortium that had IP-related terms and conditions are:

- **Employment Agreements for students** being trained for degree purposes under the program, particularly those who are registered students at more than one educational institution and who may have more than one employer.[114]
- **Material Transfer Agreements (MTAs**) concluded between the commercial company VIRCO and both UMCU and WHC.
- **Memorandum of Understanding** (MOU) between PharmAccess and the Joint Clinical Research Centre (JCRC) in Uganda, which was entered into to allow evaluation of ART-A **technologies** in a clinical laboratory setting.

#### 4.7.1 Employment Agreements

As an example, an African graduate student involved in consortium research at UMCU and therefore potentially in the generation of IP was both an employee of the WHC and PharmAccess. And at the same time, this researcher was a registered student of both the University of the Witwatersrand (WITS) and the Amsterdam Medical Centre (AMC), University of Amsterdam. Since the IP policies of the AMC and WITS are different,[115] if any IP developed by this individual was to generate revenues in future (e.g., patent royalties), there would be a lack of clarity as to how this individual would benefit and which entity would actually own the IP. Their employment contract with WHC stated clearly that "the Employee hereby assigns to the Company all intellectual property rights arising in respect of any and all works created, compiled, devised or brought into being during the course of the Employee's employment pursuant to this Contract. No consideration shall be payable by the Company to the Employee in respect of this assignment".[116] However, under terms of AMC and WITS IP policy, since these WHC employees were also registered students of the AMC and WITS institutions, the institutions would be entitled to ownership and the students would be entitled to portions of any net revenue earned. And, depending on which university IP policy

[114] In the case of students involved in ART-A research all of them were registered students as well as being employed under employment agreements with one of the consortium public or private entities.

[115] This is further discussed in section 7.3.

[116] Standard IP clause in WHC employment contracts.

applied to the students, they could have significantly different portions of revenue. Currently, if a patentable invention were to arise in which this individual was an inventor according to WITS policy, they would be entitled to 70% of net income arising from the commercialisation of IP.[117] Whereas, under AMC Research Code[118] an inventor would be entitled to 33.33% of net licensing revenues (with a cap of €1 million per inventor over the lifetime of the patent).[119] But under PharmAccess and WHC employment terms, there would be no entitlement to any share of revenue from licensing. Clearly, these are big differences in incentivisation for an inventor.

Critically, however, it is of utmost importance how ownership of inventions made by such an individual, and employed by different entities, would be determined. The current ART-A agreements do not provide for dealing with such cases and thus pose significant risk. A likely scenario is that all entities to which the student is committed would have ownership interests, but it would also likely be dependent on the capacity in which the ART-A work was being carried out by the student. Secondly, it is important to clarify under which institutional policy such an inventor would fall in order to understand how that individual would be remunerated and incentivised. Interestingly, in the case of WHC, it was established that IP developed by academics (including registered students) and scientists employed under WHC will be subject to the university's IP policy incentives in spite of the wording in their WHC employment contracts.[120] Thus, whilst it could be interpreted that inventors would fall under the policy of their primary institution, ideally this should be rectified and named at the project start to avoid confusion.[121]

### 4.7.2 Material Transfer Agreements

Material transfer agreements were concluded between the provider of materials (Virco BVBA),and the recipients of materials, namely the WHC (in March 2009) and the UMCU (in October 2009). These MTAs provided for Virco materials to be used in research under the ART-A research program. There was no cost for provision of the material and it was to be used only for research purposes at the recipient's expense. The provider was entitled to confidential access to all results of research using the material. The materials provided by Virco to UMCU had originally been provided by the University of the Witwatersrand,which had also concluded an MTA and approved the transfer of materials from Virco to UMCU.[122] The MTAs specify that the ownership of material remains the property of the provider and state that any intellectual property rights arising out of execution of the MTA, including

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117 University of the Witwatersrand IP Policy. <http://web.wits.ac.za/Academic/Research/ResearchPolicy/ip.htm> (Accessed 06 December 2010).

118 Van Kammen (2010).

119 Under AMC Research Code, where there is more than one inventor each inventor receives an equal share. AMC Research Code, p. 53.

120 This was clarified in email exchanges with WHC management but the policy in this regard is not available in any official documentation.

121 From a legal perspective, once rights are (in fact) assigned or ceded, an individual is left with nothing to assign to any other party (in respect of those same rights). So, if two contracts are signed in which someone assigns rights in the same IP, the first one will prevail, irrespective of who the primary institution is.

122 Confirmed in personal communication with University of the Witwatersrand principle investigator and documented in consortium meeting minutes.

results shall be exclusively owned by the provider. The provider is also indicated as solely entitled to apply for protection of IP rights.

These terms are in conflict with the ART-A Consortium Agreements where knowledge is property of the consortium participant carrying out research work (also allowing for joint ownership) and where the owners of knowledge are responsible for protecting that knowledge.[123] Thus, problems could arise in how to interpret this in the event of IP arising from use of these materials. In addition, it would seem unfair that IP rights resulting from use of the material originally arising from WITS should be owned by intermediary provider Virco, particularly since Virco had not added any value to the material. Whilst it was not intended that Virco would own all IP derived from use of materials provided by WITS,the MTA that was concluded does allow for that.

### 4.7.3 Memorandum of Understanding

A memorandum of understanding was entered into between PharmaAccess and the Joint Clinical Research Centre (JCRC) in Kampala, Uganda. This was to allow the parties to evaluate the ART-A HIV drug resistance testing technology and assess cost effectiveness of the methods in JCRC laboratories. JCRC provides testing services to HIV treatment sites in Uganda. From an IP perspective, it was agreed that:

1. Information concerning the ART-A program would be treated as confidential with no disclosure without written agreement by JCRC and the ART-A consortium.
2. All data and results collected during the evaluation would be jointly owned by JCRC and PharmAccess.
3. All intellectual property used in terms of the evaluation would remain the property of the party that provided it.

## 4.8 Identified Ambiguities or Conflicts in Consortium Agreements

Apart from these conflicts identified above, focus was given to the two key agreements of the consortium namely the Consortium Agreement, and the Terms and Conditions Applying to NACCAP Grants (or Funding Agreement). We identified the following key areas where limitations or potential conflicts with regards to IP might arise:

1. IP terminology used
2. Background IP
3. Confidentiality, Publication, Knowledge Dissemination and Disclosure
4. Ownership of Foreground IP
5. Protection and Costs of Knowledge and Intellectual Property
6. Access Rights
7. Commercial Use, Licensing Options and Transfer of Ownership

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[123] Described in clause 56 and 61 of the Grant Terms and Conditions available at Terms and conditions of NACCAP grants, second call. <http://www.nwo.nl/files.nsf/.../NACCAP_Terms_and_conditions_2nd_call.pdf> (Accessed 02 December 2010).

In all cases, the Funding Agreement terms and conditions prevail over conditions in the Consortium Agreement. so where conflicts were identified we considered the Funding Agreement terms and conditions to prevail.

### 4.8.1 Intellectual Property Terminology Used

A clear understanding of the intellectual property terminology used by the different parties is required and this should be aligned. Review of the Consortium Agreement and Funding Agreement highlighted differences in terminology used. Their definitions are summarised in Table 4.2. The definition of IP in terms of the funding agreement implies knowledge, yet for practical purposes IP that has useful rights associated with it tends to be considered as that which can be formally protected.[124]

**Table 4.2: Differences in Terminology between Grant Terms & Conditions and the ART-A Consortium Agreement**

| Terminology | Definition by Funder[125] | Definition by Consortium[126] |
|---|---|---|
| Intellectual Property | Not defined | Not defined |
| Background IP (consortium terminology) Pre-existing know how (funding agreement terminology) | The information which is held by the participant prior to the conclusion of the agreement | The intellectual property which is held by individual partners in this program prior to the execution of the consortium agreement, or generated in parallel with it.[127]For every part of the program this background IP will be pre-defined by each party. |
| Knowledge | All results and information generated by project activities, whether or not they can be protected, as well as copyrights or rights pertaining to such results following applications for the issue of patents or designs | All results generated in or arising out of the program that might be object of foreground IP rights |
| Foreground IP | Not defined | Means the IP arising out of this agreement |
| Confidential Information | Not defined | Information regarding the program,including background IP, knowledge and foreground IP, as defined |

[124] In broad terms, WIPO defines intellectual property as "creations of the mind: inventions, literary and artistic works, and symbols, names, images and designs used in commerce". They divide IP into two categories, namely industrial property (including patents, trademarks, industrial designs and geographic indications of source) and copyright (including literary and artistic works). Intellectual property rights are the legal rights associated with these intellectual properties. <http://www.wipo.int/about-ip/en/> (Accessed on 1 July 2011).

[125] As defined by the NWO funding agreement terms and conditions.

[126] As defined by the consortium agreement.

[127] One would assume that IP generated in parallel is also separate from the project, but this was not described as such in the consortium agreement.

| | | |
|---|---|---|
| | | below that is designated 'confidential', or the nature of such information's disclosure reasonably indicate that such information is considered confidential |
| Patent | Not defined | Any and all patents and patent applications, including all related patents anywhere in the world or claiming priority there form. |
| Access Rights Use (funders terminology) Access Rights (consortium terminology) | Licenses and use rights to knowledge and pre-existing know how. The direct and indirect utilisation of knowledge in research activities of for developing, creating and marketing a product or process or for creating and providing a service | Licenses and user rights to foreground IP or background IP |
| IP Rights | Not defined | Copyright and related rights, in particular patents |
| Research Use | Not defined | The direct or indirect utilisation of knowledge by a party on a non-exclusive basis in internal research activities |
| Commercial Use | Not defined | Direct or indirect utilisation of foreground IP for developing creating and marketing a product or process or creating providing a service. |

### 4.8.2. Background Intellectual Property

Background IP (or pre-existing know-how or information[128] or rights pertaining to this background IP as defined in the agreements) was regarded as IP owned by partners in the consortium prior to the start of the ART-A research program.It was specified that all background IP be clearly described and listed before the agreement is signed. This was background IP that is specifically required in order to perform the research program activities. This was, however, not done by the consortium members and appears to have been overlooked.

It was more important that any background IP that is being explicitly excluded also be mentioned. Since this was not done, it is likely therefore that this would only be attempted in the event of a future dispute around background and foreground IP. At this point, it could become difficult to define if proper consortium documentation was not maintained. However, reading of the agreements suggests that background IP not specifically excluded will be taken as included since in the Consortium Agreement "access rights to background IP shall be granted provided the participant is free to grant them" and "pre-identified background IP may be excluded by its owner provided it does not have a negative effect on the program." Since

[128] Background IP is described as pre-existing know-how in the Funding Agreement

no pre-identified background IP was listed, it would be assumed that there is no intention to exclude rights to use of any background IP, if any. When it comes to commercialisaton, the Consortium Agreement does not oblige the owner to "grant access rights needed for commercialisation of foreground IP."

Nowhere in the key agreements does it stipulate a requirement for how laboratory notebooks and research data should be recorded and stored. This could be necessary for: identifying background and foreground IP in the event of disagreement; quality assurance purposes in reviewing research; and determining who made inventions for patenting purposes[129]. Whilst this is most important under the US "first-to-invent" patent system, it is nevertheless also good practice to minimise and prevent disputes over inventorship that can occur if adequate record-keeping of research is not maintained.

### 4.8.3. Confidentiality, Publication, Knowledge Dissemination and Disclosure

In order that knowledge can be protected (either through formal IP protection[130] or simply as a consortium trade secret[131]) it was important that all members of the consortium understood requirements for confidentiality and procedures for disclosure and publication. The agreements cater well in setting clear requirements for maintaining confidentiality of consortium knowledge. However, since a key objective of the consortium as requested by the funder is that information generated is widely disseminated, this has to be balanced with the need for knowledge protection. Thus, the agreements provide for publication and dissemination of knowledge, provided it does "not adversely affect its protection or use."[132] And to ensure that all consortium members can review knowledge to be published, the agreement requests that all consortium members be given 30 days to review any publications. Objections to publication or request for removal of certain knowledge can be requested if it could affect the consortium ability to protect such knowledge. Publication can be delayed for up to 90 days to allow for such protection to be undertaken. These are a standard type of arrangement and are well covered by the consortium agreements.

However, they may also limit patenting strategies in the sense that sometimes longer than 90 days may be required. For example, timing of patenting is often a critical part of IP management strategies and sometimes delaying patenting can be required to allow for sufficient data to be collected or concepts developed to support applications.

To overcome the issue of publication and timing patent filings, a provisional patent filing can be considered. A provisional patent filing secures a priority date, but the provisional patent is not automatically published – at least not for 12 months – so there is no disclosure during this period. Thus, a provisional patent application can be filed prior to publication and entitles the applicant to up to one year to investigate technical and/or commercial feasibility before taking the process further. In order to obtain patent protection claiming priority from the date of the provisional application, a complete application based on the provisional

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129 Guidelines for maintaining a lab notebook [online]. <http://www.lanl.gov/orgs/tt/pdf/intell_property/nb_guidelines.pdf > (Accessed on 1 July 2011).

130 Either as WIPO defined industrial property (including patents, trademarks, industrial designs and geographic indications of source) or copyright (including literary and artistic works).

131 Definition of trade secret to be inserted here or referred to another chapter.

132 As described in the ART-A Consortium Agreement.

application must be filed within a year of the provisional filing. This may be filed in the same patent office as the provisional application, via the PCT or as a Convention application (or a combination of these).

A provisional application does not typically get published where a non-provisional/complete application based on it is filed – only the complete application is published. It will though be available in the file and can therefore be accessed under certain circumstances, on request. The key advantages of a provisional patent filing is that it is much cheaper than a national or PCT filing, less detailed information is required, there is no publication of the information and a priority date is secured. If one does not proceed to PCT or national filings then the provisional patent is never published.

Publication is also problematic for protection of a trade secret where the intention would be never to disclose. However, given the aim of this consortium, which is to disseminate the knowledge (primarily through publications), trade secrets are unlikely to be employed. In any case, trade secrets in themselves can be problematic for such a large and diverse research group where information leakage is possible. The risk to the consortium would be that a trade secret could be leaked and the same knowledge could then be formally protected, for example, through a patent by an outside third party, or could also be independently developed by someone else.

Importantly, disclosure of an invention to an institution's technology transfer office (TTO) prior to publication was not covered by consortium or grant agreements. Consortium members therefore need to be aware of their own institutional disclosure requirements in addition to the need to share information with members of the consortium. TTO offices in return would need to be aware of consortium agreements requirements in relation to the disclosure.

### 4.8.4 Ownership of Foreground IP

In any research consortium, potentially the most difficult and contentious issue can be to identify who created foreground IP and who will own it. This highlights the importance of also understanding the IP policies of each consortium member (which is discussed further in detail in Section 4.13). In this particular consortium the potential risk for uncertainty or disagreement on ownership is high, given that there are a number of parties with overlapping roles, and that the exchange of graduate students between universities, research institutes and a for-profit private company is taking place.

The Consortium Agreement and the Funding Agreement clash directly with regards to foreground IP ownership. The Consortium Agreement states that foreground IP will be "jointly owned" by the consortium members and "CPCD/PharmAccess".[133] The Funding Agreement clearly states that knowledge shall be "the property of the participant carrying out the work",[134] and, "where more than one participant generates knowledge and where the share of the work cannot be ascertained there will be joint ownership".[135] This conflict was resolved since each consortium member signed a separate Collaboration Agreement with PharmAccess stating that the terms and conditions of the Funding Agreement will prevail.

[133] Clause 62 of Consortium Agreement.

[134] Clause 56 of NACAPP Grant Award Terms and Conditions.

[135] Clause 57 of NACAPP Grant Award Terms and Conditions.

However, the problem of terms relating to IPR exclusive ownership and sole entitlement to apply for protection of IPR as described in the MTA of the commercial partner Virco remains an issue (as described in Section 4.7.2).

### 4.8.5 Costs of Intellectual Property Protection

As long as ownership of IP can be determined and agreed, the Consortium and Funding Agreements allow for the owners of the intellectual property to protect knowledge by prosecuting patents or registering other forms of intellectual property. This is with the exception of IP derived from use of Virco materials provided to WHC and UMCU as already described.

The costs of such protection are to be paid "in accordance with ownership interest of the IP".[136] What is not clear is how to protect IP if sufficient funds are not available for doing so by a particular IP owner. Costs of patenting are not trivial[137] and trying to obtain an accurate estimate of patent costs is difficult, with an absence of reliable publications providing accurate information on this[138]. Whilst patent attorneys can provide estimates of costs, they rarely give the full picture of what is required to complete the entire process and what is required to take the initial filings all the way to national filings. Often in practice, therefore, patenting costs are understimated. There are organisations like the Public Intellectual Property Resource for Agriculture (PIPRA)[139] that exist specifically to assist developing countries with patent and intellectual property rights matters, as well as practical IP and commercialisation strategies specifically for non-profit and humanitarian projects. They can be a useful resource to help plan for and manage patenting costs, as often the major costs of patenting are not the patent filing costs *per se* but rather patent attorney time costs for drafting and preparing patent documents. Since they are often charged by the hour they can be difficult to predict and budget for.

To encourage and support IP protection through filing of patenting applications, South Africa initially established a Patent Support Fund in 2005. This was later expanded to include other registrable IP (trademarks, designs, and Plant Breeder's Rights) and became known as the IP Support Fund. This IP Support Fund (IPSF) was intended to provide financial support for the IP protection costs.The IPSF does the following: provides inventors of granted South African patents registered to South African Higher Education Institutions or Science Councils a monetary incentive award; provides a retrospective payment of 50% of the costs incurred towards IP prosecution costs wherein the applicant of the IP registration is a South African Higher Education Institution or a Science Council; and grants loans towards patenting costs for inventions from South African small and medium enterprises (SMEs) or techno-entrepreneurs. More recently, in terms of South Africa's Intellectual Property Rights from

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136 Clause 6.4 of the Consortium Agreement.

137 Van Pottelsberghe de la Potterie, B. and Mejer, M. ( 2008), p. 28.

138 In part to address this, in 2009 the Directorate-General for Research European Commission called for a tender to look specifically at patent costs. See Patent costs: International comparison and analysis of the impact on the exploitation of R&D results by SMEs, Universities and Public Research Organisations. < http://ec.europa.eu/research/dgs/tenders/rtd-tender_en.cfm?tender_ref=s172-247513> (Accessed on 1 July 2011).

139 <www.piipra.org> (Accessed on 1 July 2011).

Publicly Financed Research and Development Act (No. 51 of 2008,[140] Section 13) an Intellectual Property Fund is to be established that will be managed by the National Intellectual Property Office (NIPMO). This fund will provide financial support to public institutions for protection and maintenance of IPRs.

The ART-A consortium grant funding did not include funding for patenting and therefore relies primarily on the costs of such protection to be borne by the individual consortium members who own or co-own the foreground IP. It therefore may not be possible for such consortium members to cover patenting costs affecting their ability to protect foreground IP. South African insitutions in the consortium could investigate support from the NIPMO Intellectual Property Fund. A mechanism to reduce the chances of failing to protect the IP is however included in the Funding Agreement. If an IP owner in the consortium decides not to protect knowledge then CPCD (the grant holder) would have final say in determining whether any protection should proceed or not, and may "adopt measures to protect that knowledge".[141]

This again indirectly emphasises the need of all consortium members to communicate details on publications to CPCD prior to publications being made so that they can be assessed by CPCD, the principal grant holder. It also places the responsibility on CPCD to handle the overall strategic goal of the project, including the prosecution and management of IP, to facilitate the goal of ensuring widespread access to the developed technologies in Africa.

### 4.8.6 Access Rights

Consortium agreements are clear that access rights to foreground IP will be granted to all consortium members to "enable research use at no cost".[142] In addition, background IP rights are also granted to consortium members provided the grantor can actually grant them, and that they are actually needed to conduct consortium research. Access rights to third parties can also be granted provided that access rights for consortium members are not affected. Importantly, the agreements also provide for consortium members to have continued access rights to background IP required for the duration of the research program even if that member granting access leaves the research consortium.

### 4.8.7 Commercial Use Licensing Options and Transfer of Ownership

This is an important aspect of the consortium intellectual property arrangements. If the technology developed is to be used commercially or ownership of the IP is to be transferred out of the consortium, then it needs to be clear how this can be done and how, at the same time, to protect the use of and access to technology in Africa. The agreements in this regard are somewhat confusing and are discussed bearing in mind that the Funding Agreement should prevail over the Consortium Agreement.

The Consortium Agreement suggests that consortium members can seek third parties willing and able to commercially use foreground IP. That foreground IP can be licensed

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140 South Africa. 2008. *Intellectual property rights from publicly financed research and development Act, no. 51 of 2008.* Pretoria. Government gazette. <http://www.dst.gov.za/publications-policies/legislation/IPR%20Act%200f%202008.pdf> (Accessed on 1 July 2011).

141 Clause 62 of NACAPP Grant Award Terms and Conditions.

142 Consortium Agreement Clause 6.3.

(including rights to sub-license to other third parties) for commercial use on exclusive or semi-exclusive terms, but not in the territory of Africa.[143] A transfer of ownership of foreground IP to the third party can be negotiated, but it is not clear how such a transfer of ownership can prevent commercial use in the territory of Africa. In addition, before such transfer of ownership can occur, the other consortium members have right of first refusal to that IP. Any transfer of rights cannot be allowed to obstruct a consortium member's rights to use that IP for research purposes.

The Funding Agreement states that African commercial institutions who are consortium members (in this case WHC) can only transfer their foreground IP to a "European affiliated" party if compensated at "market price". No mention is made of transfer to non-European parties or how market price would be determined.

The Funding Agreement is clear on the fact that if consortium members transfer rights in foreground IP it must conclude agreements with the same obligations in terms of access rights, dissemination and use. Other consortium members can object to such ownership transfer to third parties if it does not serve the interests of the program or their access rights.[144] It does not, however, exclude commercial use in Africa.

It is difficult therefore to interpret exactly how consortium members could go about licensing or transferring IP rights to a third party who wishes to use these rights in Africa, as the Funding Agreement and Consortium Agreement offer different angles on this. Clearly, the intention of the agreements is to prevent licensing that could result in excessive profit exploitation of the technology in Africa and the resulting higher costs. However, it has the potential unintended consequence of limiting the ability to actually make the product available in Africa by an African, international or other commercial partner. It is likely that resolution of this would require the funder and the consortium members to amend the agreement to allow licensing to an African commercial entity if it was deemed to be in the interest of access.

It also highlights again the need for competent and experienced TTOs in both European and African institutions to play a significant role in understanding and using consortium agreements for their desired effect.This supports the need for grants that support technology research and development to, in parallel, provide for further capacity development of African TTOs – in particular to formulate agreements that do not hinder access to the developed technology in Africa. In the absence of the abilities to effectively manage intellectual property created by such consortiums, the full benefits of technology may not be realised.

### 4.9 Intellectual Property Policies of Institutional Consortium Members

It is also important to take into consideration the intellectual property policies of the different institutions participating in the consortium. Whilst commercial enterprises (like Virco) generally make reference to ownership of intellectual property in employment contracts,[145] public institutions and universities generally have intellectual property policies or research codes that describe ownership and revenue sharing or other incentivisation systems for IP

[143] This is an interpreted summary of clause 6.4 of Consortium Agreement.

[144] An interpreted summary of clause 60 of NACAPP Grant Award terms and conditions.

[145] Most commercial company employment contracts state that any intellectual property is owned by the employer and that employee assigns all rights and interest to the employer.

developed by institutional employees or students.[146] This has become commonplace, particularly as the participatory role of TTOs within public institutions has increased.[147] It is most often the institutional TTOs that draft and implement the IP policy with input from stakeholders and the approval of that insitution's governing body.[148]

To identify conflicts in policy and specific policy terms that might hinder the ART-A consortium goals or not fit with the ART-A consortium agreements the collaborating institutions' IP policies or research codes were reviewed where available (Table 4.3).[149] It is difficult to assess the alignment of all policies since a number of policies were under revision or review, but as they stand they do allow for the flexibility to address the stated goals and agreements of ART-A. Also, because the coverage of all IP areas differed in the policies, it was not always possible to do direct comparisons, but the key areas were covered (as summarised in Table 4.4) and where significant differences or unusual conditions were identified they are discussed below.

**Table 4.3** ***ART-A Collaborators' Institutional Intellectual Property Policies or Research Codes***

| Institution | Policy Status | Public Location or Source |
|---|---|---|
| Centre for Poverty-related Communicable Diseases (CPCD), Amsterdam , Medical Centre (AMC), University of Amsterdam, Amsterdam, The Netherlands | IP policy is detailed in AMC Research Code first published in October 2001 and 3rd revised edition published March 2010. | http://www.amc.nl/?pid=7854 |
| University Medical Centre Utrecht (UMCU), Utrecht, The Netherlands | IP policy is not online and currently under review.[150] UMCU whilst closely related to University of Utrecht is a separate legal entity. | http://www.uu.nl/uupublish/content/UitgangspuntenUUinzakesamenwerkingeneng.doc |
| Centre de Recherche Publique- Santé (CRP- Santé), Strassen, Luxembourg | IP policy is currently under revision and not available online[151]. | Not currently available |
| University of the Witwatersrand (WITS), Johannesburg, South Africa | IP policy is publically available as a specific research policy since January 2003. | http://web.wits.ac.za/Academic/Research/ResearchPolicy/ip.htm |

146 Patent law and employment law also provides guidance in this.

147 Krattiger, A. (2010), pp. 573-575.

148 Amsterdam Medical Centre Research Code (2010).

149 The parties PharmAccess Foundation and Virco BVBA do not have IP policies and rather specify in their employment contracts that they are the owners of all intellectual property rights related to or derived from the work of employees.

150 We used the IP policy document of University of Utrecht as supplied by the technology transfer office of UMC Utrecht Holding BV.

151 We used the draft IP policy as supplied by the CRP-Santé technology transfer office.

| | | |
|---|---|---|
| Wits Health Consortium (Pty) Ltd (WHC), Johannesburg, South Africa[152] | Intellectual property rights are outlined in employment contracts which state that all IP and associated rights are owned by the WHC However, IP developed by WHC employees who are also students or academic staff of the University of the Witwatersrand are subject to the University of the Witwaters-rand's IP policy which prevails over the employment contract with respect to IP clauses[153]. | Not applicable |

**Table 4.4** ***Scope and Differences in IP Policies of Public Institutions Collaborating on ART-A***

| Areas Covered | AMC Research Code | UMCU IP Policy[154] | CRP-Santé IP Policy | University of the Wit-watersrand Research Policy |
|---|---|---|---|---|
| Definition of IP | Not specifically defined but includes research findings, copyright, software, patents, trademarks, designs and models | Not defined but covers knowledge and research findings | Not defined | Know-how, software, trademarks, designs, names and insignia, copyright and other confidential matters and trade secrets[155] |
| Obligation or requirments for IP disclosure | Researchers are advised to consult the TTO on inventions but patents on AMC inventions are filed and maintaiend by the TTO. | Not defined and appears that there is no obligation to disclose inventions although there is obligation to protect knowledge by the university. | Employees and covered individuals are contractually obligated to: disclose promptly to CRP-Santé any intellectual property. In case of a patent application, the inventor(s) will promptly fill out an invention disclosure form. This also includes disclosing any CRP-Santé Intellectual Property to the CRP-Santé TTO prior to disclosing such discoveries or inventions through publications, | IP belonging to the university and not in the public domain may only be disclosed with the permission of the Vice-Chancellor, any Deputy Vice-Chancellor, the university's Registrar or the Dean of the Faculty in which the IP arose. Improper disclosure may adversely affect the patenting and registration of inventions or the protection of other confidential information. |

152 WHC is a wholly owned subsidiary company of the University of the Witwatersrand.

153 This information was verified by the WHC, CEO and the University of the Witwatersrand technology transfer office when it was identified that there was a conflict for WHC employees who were either students of the University or University academic staff between their WHC employment contracts and the University IP policy in terms of IP ownership and associated rights.

154 This is actually the terms of the University of Utrecht.

155 Interestingly patents are not listed.

| | | | | |
|---|---|---|---|---|
| | | | presentations, or communications with third parties (including research sponsors). | |
| Ownership of IP (or Research Findings) | Publications – owned by author[156] but ownership claimed by AMC. Know-how, materials and inventions owned by AMC unless specified otherwise | Property of party generating the knowledge and unless specified by agreement is UMCU | Property of CRP-Santé unless waived or assigned by Board of Directors and TTO. Waives claims to copyright for publications | Property of institution but also specifies students and employees who are visiting other institutions may confer ownership rights in research to WITS.[157] Students not under supervision by WITS employee excluded. |
| Ownership of IP from joint research | Provision for multiple party ownership | Provision for multiple ownership | Provides for this in collaboration agreements | Provision for multiple ownership but stipulates ownership share in proportion to relative contribution[158] |
| Need for knowledge protection | Appropriate protection when required | Appropriate protection when required | Acknowledge and provided for with requirements for disclosure | Acknowledge and provided for with requirements for disclosure |
| Costs of protection | Borne by owner of IP | Borne by the owner of IP | Not specifically mentioned but implied in terms of disclosure requirements | Not clear but university pays for patent costs for inventions that it considers worthy of patenting |
| Allowance for additional agreements for commercialization or transfer of knowledge | Allowed and flexible | Allowed and flexible including licensing or transfer on market terms | Allowed and flexible | Allowed and flexible. |
| Respect and need for confidentiality | Identified and discussed | As long it does not jeopardise academic integrity and publication | Use of MTAs and CDAs is compulsory | Identified and addressed in terms of disclosure requirements |
| Publication delays to allow for IP protection | Delays longer than 90 days are considered unreasonable[159] | Suspension of publication for up to no longer than 90 days | Not specifically mentioned but implied in terms of disclosure requirements | Information may be kept confidential for period provided by University rules. In addition if student has not |

156 Van Kammen (2010).

157 No conditions are specified.

158 This has not yet been amended to include provision for ownership by government in terms of the new South African Intellectual Property Rights from Publicly Financed Research and Development Act 51 of 2008.

159 Van Kammen (2010).

| | | | | |
|---|---|---|---|---|
| | Author of dissertation can request 6-12 month publication embargo to prepare publication | | | published thesis within 24 months student assign all copyright to the university |
| Retention of rights for research use | Rights for research use should be included in agreements | Must always retain rights for research use | Not mentioned | Not mentioned |
| Revenues derived from IP | Has differences in revenues allowed to inventors for patents, software and patented technology commercialized through a spin-off company | Agreements negotiated to decide no recommendations provided | Subject to negotiation. No guidelines or limits specified | The most generous allowing for originator to receive 70% of net income and the university 30% |
| Liability requirements | Must be considered in all agreements | All agreements must have exclusion of liability | Not covered | Not covered |
| Applicable law | Dutch law | The Netherlands | Not covered | Not covered |

### 4.10 Ownership of Research Findings and Confidentiality

Policies were all similar with regard to confidentiality, as well as publications and inventions owned by the employer or institution at which a student was registered, unless separate agreements were entered into that allowed for alternative ownership structures.

Interestingly, WITS included a clause whereby WITS waives ownership of IP generated by students not under direct supervision by WITS employees. And CRP-Santé policies actually state that use of MTAs and CDAs is compulsory, which is stricter than the recommendations in the other policies.

### 4.11 Revenues from Patents, Licenses and Companies

This is the area where the most obvious differences in reward and incentives for employees and academics from different organisations were noted. In the context of a consortium like ART-A, whilst this does not affect the consortium directly since such revenues would first go to the institution and then the institutional policies would apply the rewards to the employees or students. However, because there are some big differences in reward these could create

personnel problems and affect institutional loyalties. For example, a researcher under WITS policy would receive 70% of net income from a patent with no cap on the income, in contrast to an AMC researcher who would receive on 33.3% with a €1million cap on income. Whilst unlikely to be an issue for the ART-A consortium, it is worth being aware of such differences and how it could affect morale or motivation in a consortium.

### 4.12 The Role of TTOs

The intended role of institutional technology transfer offices (TTOs) is well summarised by the AMC research code[160] and is expanded in the case of South Africa whereby the function of public institution TTOs is described by the Intellectual Property Rights from Publicly Financed Research and Development Act[161] discussed in Section 4.10.These roles include:

- Developing policies for IP and IP management at institutions
- Handling and analysing IP disclosures, to assess commercial potential and appropriate IP protection strategies to be used
- Providing expert advice to institutional researchers on how to exploit IP
- Drafting and executing agreements especially CDAs and MTAs, but should also include collaboration agreements where IP is involved
- Determining and providing for IP protection costs (e.g., patenting), where necessary or deemed viable or worthwhile
- Management of IP commercialisation (licensing or transfer)
- Creating or managing start-up companies

These roles tend to be well aligned with the role of TTOs at the University of the Witwatersrand in South Africa almost identical to that of University of Amsterdam, as one example. There is also a growing awareness in more experienced and older TTOs in public sector institutions that they can and should play more of a role in supporting development and broader institutional goals, in addition to trying to manage IP for the sole purpose of revenue generation.[162] This tends not to be the case in less experienced and newly established TTOs that often need to justify their existence with revenues in the short term. It has been shown in the case of some developed countries with TTOs that have been established for a longer period that they actually tend to support social and academic goals through the management of the IP of their institutions rather than specifically generating income *per se.*[163] This is a complete reversal of the Association of University Technology Managers[164] (AUTM) position in the 1990s and TTOs, particularly those being established in Africa, should be aware of this so as not to fall into the same trap. In fact, income generation, where the TTO actually covers costs and then makes money, can take years and also tends to be highly variable

160 Van Kammen (2010).

161 South Africa. 2008. *Intellectual Property Rights from Publicly Financed Research and Development Act, No. 51 of 2008*. Pretoria: Government Gazette. <http://www.info.gov.za/view/DownloadFileAction?id=94343> (Accessed on 1 July 2011).

162 Krattiger, A. (2010), pp. 573-575.

163 Bubela, T. M. and Caulfield, T. (2010), pp. 447-451.

164 Association of University Technology Managers [online].<http://www.autm.net> (Accessed on 1 July 2011).

between institutions in terms of revenues generated.[165] The high profile cases tend to make the news and create unreasonable expectations of revenue expectations for TTOs at other institutions. Studies of licensing returns at US universities showed that only a few US universities make significant returns; many having negligible or negative returns.[166]

It is clear after review of the ART-A IP consortium agreements that TTOs can and must play a significant role in the development, the finalisation and the management, of effective consortium agreements for each institution. A potential problem arises in consortiums between institutions that have TTOs with very different resources, expertise and experience. For instance, simply being able to review and understand the IP arrangements of the ART-A consortium requires considerable human resources, expertise, time and understanding of consortium issues. Disparities between TTOs in these areas can result in institutions lacking these resources not being able to effectively manage these agreements in their best interest and therefore relying on the benevolence and goodwill of the funding agencies in the developed world that, despite good intentions, may not have full understanding of issues at the relevant institutions.

Therefore, more investment is also needed in developing the capacity and expertise at TTOs in the less developed countries where consortiums like ART-A operate. In essence, equalisation of the international legal systems does not necessarily translate into effective application, where resources, knowledge and experience in IP management is lacking. One can often forget that management of IP in itself also requires significant resources in addition to technological research and development.

### 4.13 Key Lessons in Consortium IP Arrangements

Review of the consortium agreements with respect to IP arrangements highlighted the fact that management of consortium IP can be a complex issue.
In brief summary, the following lessons can be extracted and should be considered by consortiums or PPPs that are seeking to minimise conflicts over IP and ensure clarity in handling of IP-related issues:

- All parties involved should be signatories to all relevant agreements at all times and their correct legal names used. Contracts must be signed off by duly authorised signatories. In complex arrangements with many different parties a party can be excluded if all agreements are not properly mapped. This requires competent legal staff in the partnering institutions and especially the lead institution.
- When a researcher has more than one employer there needs to be a clear way to identify who the owner will be of any IP developed by that researcher.
- Where researchers involved in generating IP (students or employees) are employed by more than one entity then either, the terms and conditions covering remuneration and incentive options should be aligned, or a separate agreement should be concluded with those individuals to ensure that it is clear which terms and conditions would apply to them.

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165 Technology transfer tactics [online]. <http://www.technologytransfertactics.com/content/2009/02/04/autm-releases-latest-licensing-survey-data/> (Accessed on 1 July 2011).

166 Bulut H. and Moschini G. (2006).

- Ideally terminology used in defining terms and conditions should have the same scope and meaning. One cannot read the consortium agreements without also looking at the terms and conditions of the grant, as in many cases there are contrary requirements and in most cases the grant terms and conditions override terms and conditions in the original consortium agreement.
- If background IP is to be brought into a consortium, such background IP should be properly defined and not just broadly mentioned. It is recommended that standard practice should dictate that any background IP to be excluded is actually listed and failing that, access to background IP that is required for consortium activities is given provided the giver has the rights to do so.
- Consortium agreements should always include details on how research or laboratory notebooks are to be maintained and stored to help determine timing of inventions and identifying inventors, which is critical to determine ownership of IP. If this is not done it could compromise IP protection potential and it cannot be assumed that each party will keep proper documentation without specifying requirements.
- It is advisable that institutional TTOs are involved in analysing and reviewing all agreements that apply to the consortium, prior to their finalisation. The discovery of MTAs and MOUs that were signed during the course of consortium research that were not properly aligned with the consortium agreements highlight the role that TTOs can play in ensuring that this does not happen. Ideally, institutional TTOs should appoint an agreements manager for consortiums that can review agreements in the overall context of the consortium. Of biggest concern was the MTA signed with the commercial partner Virco and the two consortium members WHC and UMCU that could create IP ownership issues into the future.
- It is necessary that TTOs of consortium members have legal expertise to be able to interpret legal clauses and their meanings in the various agreements. Outsourcing is also an option, especially where an institution deals with a low number of collaborations and may not be able to justify the costs of this expertise being made available on a permanent basis.
- The country of applicable law of agreements tends to be determined by the largest partner, or partner that controls the funds, but this does not necessarily serve all consortium members. Consortium members in other countries need to be aware of how accepting such terms could affect their roles and their future negotiating positions. In practice, it would be unlikely that an African research institution would have the resources to argue a position in relation to a consortium agreement in a court in the Netherlands.

# CHAPTER 5 ENSURING ACCESS TO ART-A TECHNOLOGY

## 5.1 Introduction

The intention of this section is to investigate the strategic options that ART-A could follow to ensure that it can meet its objective of ensuring widespread access to the technology in Africa. We assess the actual direct IP implications of these options with a matrix model to assist and inform decision-making by the ART-A consortium.

The consortium received funding that covered HIVDR testing method development and assay evaluation, but strategies are needed to ensure that access to research information and technology generated by the consortium can extend to others beyond its funded life.This requires that we examine how to identify the best IP protection strategies that ART-A can actually use based on the technology developed, and then investigate how IP rights (either of the consortium or third parties) may influence decisions on which options are advisable for ART-A. This assessment is undertaken by looking at the context (the technologies, laboratory requirements and regulatory issues), IP protection options (including how to handle publications), freedom to operate (internally and with third parties), and other issues (including any particular policies or laws) that may have a direct bearing on ART-A's ability to ensure access.

## 5.2 Non-IP Considerations

### 5.2.1 Technical and Lab Facility Considerations

Different laboratories in Africa possess the ability to use all or some of the technologies developed for monitoring of antiretoviral treatment and measuring HIV drug resistance. At the same time, many such laboratories have specific technical constraints that need to be understood. Laboratories need to have the expertise, equipment, reagents and consumables to perform testing. Training of laboratory staff to perform complex molecular tests where staff turnover is high, and providing all the necessary equipment for testing as well as standardisation and quality control remains an issue. These continue to be addressed by laboratory capacity building and accreditation programs in Africa that need to be expanded and strengthened.[167]

One of the biggest challenges to laboratories in Africa is consistent supply of the required test consumables and reagents, as well as the service and maintenance of laboratory equipment.[168] In complex molecular testing protocols like HIV drug resistance testing, where a large number of separate items from different suppliers are required, lack of supply of a single reagent or consumable can prevent tests from being conducted.

Also, the affordability of such testing is debatable and trying to determine at what price per test HIVDR testing becomes affordable in Africa is difficult, even if such tests in development are often described as "affordable".[169] Because of the high costs, it is more likely that in Africa HIVDR testing will be used more often for HIV drug resistance surveillance and

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167 Nkengasong, J. N., Nsubuga, P., Nwanyanwu, O., Gershy-Damet, G. M., Roscigno, G., Bulterys, M., Schoub, B., Decock, K. M. and Birx, D. (2010), pp. 368-373.

168 Masanza, M., Nqobile, N., Mukanga, D. and Gitta, S. (2010), S8.

169 Wallis, C. L., Papathanasopoulos, M. A., Lakhi, S., Karita, E., Kamali, A., Kaleebu, P., Sanders, E., Anzala, O., Bekker, L. G., Stevens, G., De Wit, T. F. and Stevens, W. (2010), pp. 505-508.

to monitor HIVDR at a population level rather than for making individual patient treatment decisions.[170] However, technologies that help to lower costs increase the chances of improving affordability and help increase competition, thereby driving down prices. Tests that are already costly, when encumbered with additional licensing costs, simply increase these costs. This means that in addition to improvements in technology or new technologies to lower costs, ways to reduce the additional costs imposed by IP rights (e.g., license royalties) are needed.

### 5.2.2 Regulatory Considerations

Understanding of regulatory issues as regards human *in vitro* diagnostics (IVD) is required to inform decision-making particularly around the need for accurate terminology in any licensing of assay components required for IVD use. Currently in the US and Europe there are regulations governing medical devices, whose definition includes any "*in vitro* reagent" or "software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purposes of diagnosis, prevention, monitoring, treatment or alleviation of disease".[171] Products intended for human *in vitro* diagnostic (IVD) use must be approved before they can be sold to ensure they meet the requirements for this use. This is the standard applied to commercially available diagnostics assays (and includes the commercial HIV drug resistance assays already described).

Kits and reagents can also be sold and marketed as Research Use Only (RUO) or Investigational Use Only (IUO) and as such have less stringent regulatory requirements.[172] In practice, many clinical laboratories actually use reagents sold commercially for RUO purposes as part of "in-house" tests they develop in their own laboratories. These are referred to as Laboratory Developed Tests (LDTs) where the laboratory offers a testing service rather than selling a test kit. Such an approach is being followed by ART-A in procuring reagents that are marketed and sold for RUO, but are used in ART-A methods to produce clinically useful diagnostic test results. LDTs tend to be regulated through established clincial laboratory accreditation standards. In South Africa for example, clinical laboratory standards are assessed by the South African National Accreditation Service (SANAS).[173] To discourage RUO reagents (which are not required to be GMP manufactured) from being used in LDTs, another classification called Analyte Specific Reagents (ASRs) was introduced in the US.[174] These are regulated by the FDA to ensure quality of the reagents used in LDTs in the US[175]. These are important distinctions to be aware of particularly when licensing such products from US-based manufacturers who may not realise that requirements in Africa are different.

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170 Jordan, M. R., Bennett, D. E., Bertagnolio, S., Gilks, C. F. & Sutherland, D. 2008. World Health Organization surveys to monitor HIV drug resistance prevention and associated factors in sentinel antiretroviral treatment sites. *Antivir Ther,* 13 Suppl 2**,** pp. 15-23.

171 WHO. Medical Device regulations: global overview and guiding principles (2003). <www.who.int/medical_devices/publications/…/MD_Regulations.pdf> (Accessed on 1 July 2011).

172 Thompson, B. (2010).

173 To conform to international standard ISO 15189:2007.

174 ASRs are required to be manufactured according to Good Manufacturing Practice (GMP) principles.

175 <http://www.fda.gov/cdrh/oivd/guidance/1590.pdf> (Accessed on 1 July 2011).

In Africa there are no promulgated regulations yet governing IVD testing, but this is due to change in time as there is a continent-wide move to improve the quality of diagnostics through both laboratory accreditation[176] and a global movement to ensure harmonisation in the regulation of medical devices.[177] In South Africa, the newly created South African Health Products Regulatory Authority (SAHPRA), which replaced the former Medicines Control Council (MCC), is to be mandated to regulate medical devices in South Africa.

Where the ART-A assays and their components are classified and how these will be regulated will depend on what regulations are promulgated and enforced in South Africa and other African countries. ART-A assays are in essence LDTs, since they are methods employed in individual laboratories with individual RUO components purchased separately. The ART-A consortium could be considered to be the "laboratory" developing the test. Therefore, when licensing components from US manufacturers who are regulated differently, an understanding of what classification they could be licensed under can influence the license obtained and fees negotiated.

## 5.3 ART-A IP

ART-A IP developed by the consortium (described in Section 2) consists of methods, materials and/or software developed for:

- Collecting storing and transporting patient dried blood spots and plasma.
- Methods for extraction of nucleic acids
- Methods for amplification and quantification of viral nucleic acids
- Methods for amplification and sequence determination of HIV genes important for drug resistance.
- Software for accurately determining sequence data and generating inferred drug resistance mutations that can be used to submit data for generating HIV drug resistance reports for managing patient treatments

All of these methods cover knowledge generated by the consortium, and hence consortium foreground intellectual property. This includes: novel DNA primers; amplification and sequencing conditions optimised for sensitivity and detection of subtypes of HIV relevant to Africa; modifications to protocols that increase detection of dried blood spot samples; and information that can enable users to perform drug resistance and viral load testing from dried blood spots.

## 5.4 Identifying IP Protection Options Suitable for ART-A

The different forms of IP protection available are discussed in Annex III but the actual options ART-A would be advised to use are discussed below in relation to the strategic plans for ensuring technology access from an IP perspective. Table 5.1 summarises options and assesses the pros and cons of the different forms of protection that are discussed in Annex III in relation to different components of the technology offering.

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176 Opio, A., Wafula, W., Amone, J., Kajumbula, H. and Nkengasong, J. N. (2010), pp. 381-387.

177 Powers, D. M. 2000. Towards global in vitro diagnostic standards, Part II. *Med Device Technol,* 11, pp. 41-44.

### 5.4.1 Patents

The ART-A consortium conducted a review internally of all methods developed to identify patentable inventions based on the requirements of patentability.[178] Each of these methods was segmented into the steps involved to assess if any of the steps could be regarded as novel and inventive, as well as the combination of steps or concepts as a whole.[179] Potential patentable inventions identified included novel amplification and sequencing primers and the unique areas if the HIV genome amplified and sequenced for HIVDR determination. Preliminary patent searches revealed a large number of patents in this area covering methods for HIV sequencing and genotyping.

As examples, in the public sector, the Centers for Disease Control and Prevention (CDC)[180] in Atlanta, Georgia US, has filed for patents for similar concepts and in the private sector, the US-based Applera Corporation[181] has a family of patents for HIV sequencing and genotyping that cover amplification of HIV using primers that differ, in one case, only by a few nucleotides from an ART-A primer.[182] Purchasers of the commercial HIV drug resistance assay (Viroseq™ HIV-1 Genotyping System) manufactured by Applera's subsidiary Celera receive a limited license to use this product for human diagnostics. The commercial partner in the ART-A consortium ,Virco has a number of patents covering claims for HIV amplification and sequencing primers.

**Table 5.1** ***Type of IP protection with respect to different components of ART-A technology***

| **Technology Component or Method** | **Type of Protection[183]** | | | | |
|---|---|---|---|---|---|
| | Open Access | | Protective Commons e.g. BiOs type license | Trademarks | Patents |
| | Publication/ Copyright | Open Source[184] | | | |
| Dried blood spots collection and storage | Suitable for general scientific publishing of results | Good for specific protocols as ensures additional rights and under attribution license ART-A acknowledged | Possible but not practical for wide lab use across Africa. Too cumbersome and difficult to administer | Good option since ART-A consortium publications support the methods | Not patentable as ART-A technologies in this area not novel |

178 Patentability requirements are described in Chapter 6.

179 This was done by PharmAccess in consultation with consortium members.

180 Centres for disease control and prevention [online]<www.cdc.gov>.

181 <www.applera.com> (Accessed on 1 July 2011).

182 This was identified by searching ART-A amplification and sequencing primer sequences on the free Sequence Search Facility provided by CAMBIA's Patent Lens Sequence project which actually allows one to search for sequences in US patent claims.<http://www.patentlens.net/sequence/blast/blast.html> (Accessed on 1 July 2011).

183 Trade secrets are not considered since they are not suitable for the consortium as they restrict information flow and are unlikely to be able to be contained due to nature of the consortium.

184 Creative Commons or GNU GPL or a range of other open source type licenses.

| | | | | | |
|---|---|---|---|---|---|
| Extraction of nucleic acids | Suitable for general scientific publishing of results | As above | As above | As above | Not patentable as above |
| Methods for amplification and quantification of viral nucleic acids | Suitable for general scientific publishing of results | As above | As above | As above | Patentable aspects but potentially weak[185] (e.g., novel amplification primers) |
| Methods for amplification and sequence determination of HIV genes important for drug resistance | Suitable for general scientific publishing of results | As above | As above | As above | Patentable aspects but potentially weak (e.g., novel sequencing primers and region of genes to be sequenced) |
| Software for accurately determining sequence data and generating inferred drug resistance mutations | Weak option | As above | As above | As above | Not patentable in African territories |

[185] In light of prior art.

Inventing around primer sequences by modifying them slightly is possible and in a sense, the ART-A consortium has invented around the Applera patents by using different primers and amplifying a different area of the genome. Therefore, given costs of patenting for the consortium and individual consortium members, a more detailed analysis of the patents in this area is required before a final decision can be made to determine if patenting ART-A inventions could have value. A tool for this is the Cambia Patent Lens Sequence Project sequence search facility tool that allows one to search sequences that are in the claims of US patents[186]. This is, however, time-consuming and requires skills and resources to be allocated to doing this, which can be difficult to mobilise in a consortium of this nature where different members have different capabilities. Thus it is generally recommended that patent searches are conducted by and contracted to professionals in this area, usually an intellectual property law firm that specialises in offering this service.

ART-A patenting decisions must also be considered in light of ART-A's need to protect its freedom to operate (e.g., preventing third parties from making improvements to the technology and securing patents on which ART-A may infringe the claims; thus any decision not to patent must be carefully considered. The use of defensive publication could also be considered as a means to prevent others from securing rights to the technologies and would form part of the public domain stratgey already described.

In addition, if ART-A is to patent, the question is, in which territories should it do so? With patenting of ART-A technology the option exists to license technology to a manufacturer of a commercial assay either to a new market entrant or to a current manufacturer. This may in fact be possible as the ART-A technology represents improvements on the current commercial assays. So provided that inventorship and ownership can be agreed by consortium members, which is potentially complex with such a diverse group, a recommendation would be to file a key patent on the core technology or to at least let this be an option. To assist in this process, a basic patenting decision tree can be used (Fig. 5.1) but there could be many more options and thus this serves as a guide only.The use of provisional patent applications is also an important option and is described in Section 4.9.2.

### 5.4.2 Trade Secrets

Trade secrets are in our view not a viable option for ART-A as they do not support consortium members desire to publish in scientific journals, to ensure information is accessed and "secrets" in any case would be very difficult to ensure or guarantee in such a large, diverse and largely academic research group.

[186] Ibid.

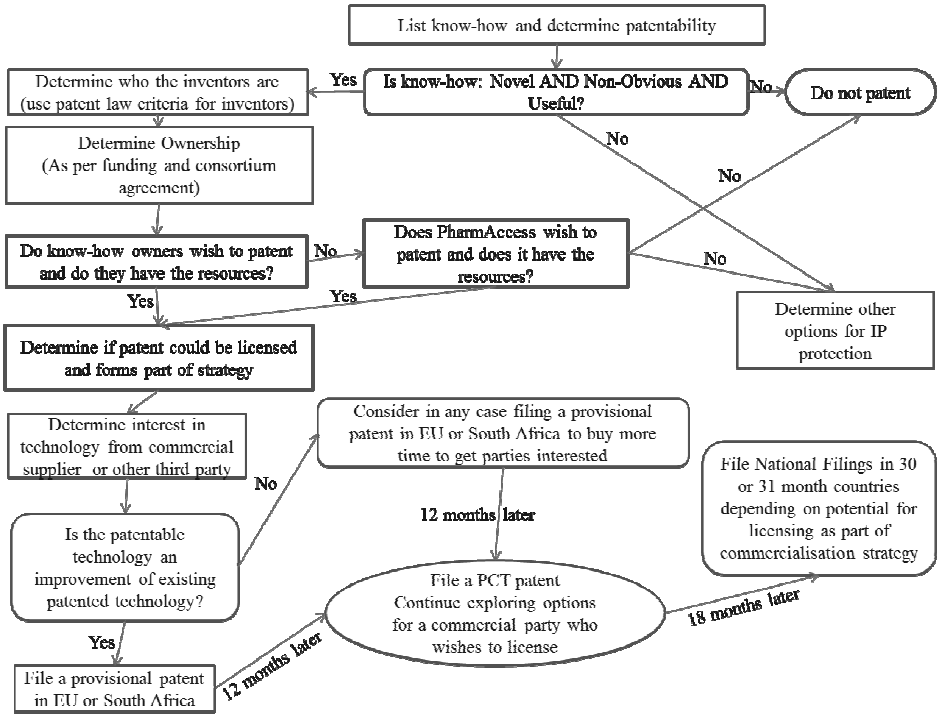


**Fig 5.1** ***Patenting decision tree***

### 5.4.3 Trademarks

Trademarks are "distinctive signs used to differentiate between identical or similar goods and services offered by different producers or services providers".[187] A registered trademark becomes a type of industrial property that is protected by intellectual property rights. This can include a brand name, slogan, logo or even images or shapes. Trademarks are registered at a national level. For instance, in South Africa, trademarks are registered with the South African Companies and Intellectual Property Registration Office (CIPRO).[188] Once a trademark is registered, nobody else can use a similar trademark and the trademark is protected for as long as it is renewed and renewal fees paid.

The use of trademarks is a viable option for consideration by the ART-A consortium for creating brand awareness around the HIV drug resistance technologies that they are developing. Firstly, ART-A has already established a brand presence in a number of key laboratories in African countires that have been exposed to technology training and HIV drug resistance workshops. Secondly, ART-A has already published the results of some of its work in both peer-reviewed scientific journals and at key scientific conferences. This provides referencing of ART-A work to these publciations giving the ART-A brand credibility in the HIV drug resistance testing field. Thirdly, ART-A has a distinctive logo (Fig. 5.2) and has been maintaining a distinctive website (www.arta-africa.org) to keep all laboratory users up to date

187 WIPO. <http://www.wipo.int/trademarks/en/> (Accessed on 1 July 2011).

188 <http://www.cipro.gov.za/products_services/trademarks.asp> (Accessed on 1 July 2011).

in the technology. So there is already brand recognition among key HIV drug resistance testing laboratories in many African. Given the consortium members are also well recognised institutions and companeis that have brand rcognition in their own right this helps to strengthen the ART-A brand.


**Figure 5.2** ***ART-A logo which incoporates the slogan "Affordable Resistance Test for Africa"***

Thus, registering trademarks to ART-A name and logo would have value in both terms of recognition of ART-A and in terms of quality. To that end users would know that the development is backed by acknowledged HIV drug resistance testing expertise at major institutions. Potentially, ART-A could register trademarks in the key countries where the technology is to be used in Africa and then depending on the strategy employed for sale or supply of the ART-A technologies such a trademark could be used (under license) by a commercial supplier or other distibutor of the product be it a service offering or actual testing kit. This would provide confidence to end users. Other parties would not be able to use the ART-A mark even if they used similar technologies because they would not have the rights to the trademark.

### 5.4.4 Open Access

Open access options can be divided into public domain and open source. Both have a role to play in the distribution of and access to ART-A technologies. Here we present a model that ART-A could use, using an interplay of both public domain and open source publication (but which requires that the technology is protected by IP rights in order for it to be open source).

#### 5.4.4.1 Public Domain Publication

Publication of patentable ART-A information in scientific journals would mean that it enters the public domain where noone owns the information, if the ideas are disclosed. This is a useful way to make laboratories aware of technologies for HIVDR. Publications could disclose all the information in detail.

Alternatively, publications could focus more on the results of technology, i.e., sensitivity and performance of assays rather than the detailed methods of doing the assays. The publication could even refer to an ART-A website where methods are available as downloads. This would be a little bit like the common practice of providing for supplementary information except in this case the supplementary information would be provided under a separate download. The terms of download could be determined by ART-A – a fee could be charged, or no fee but with registration details required. In addition, the ART-A software could be provided as a separate download under an open source type license described below.

ART-A would preferably use publications that provide for use under a Creative Commons Attribution License,[189] since often testing laboratories are not able to pay journal subscription fees and therefore are not able to access journals that require subscription. This way, laboratories get access to peer-reviewed independent analysis on the performance of the technologies and at the same time detailed SOPs and software to perform the tests.

#### 5.4.4.2 Open Source for ART-A Software

Open source licensing is generally applied to software and would be a license that allows the user to reproduce, modify and distribute the software for free.[190]A fee can be charged for the distribution but no royalty is payable to the original copyright owner. This could be applied in particular to the software developed under the ART-A program. Importantly, the ART-A software was developed using a number of open source software tools that themselves are governed by GNU general public licenses (GPL)[191] and therefore the ART-A software is subject to terms contained therein. The GPL license is an open source license that has an additional requirement that any improvements must be made freely available to any other users. So because ART-A software developed by the consortium is subject to the GPL license this condition applies.

The licensor (ART-A), would agree not to prevent licensees (i.e., African laboratories) from using, improving or sharing the technology, which should help to encourage labs to adopt the ART-A technologies.

### 5.4.4 Protected Commons

This would refer specifically to the BiOS approach[192] that allows a secure platform for improvement of technology to take place that prevents misappropriation by third parties through standardised licensing agreements. This has been done in the case of BioForge which is an online information portal that has been applied to a number of projects including deevloping of new methods of gene transfer to plants, clonal reproduction of plants and reporter gene vectors amongst others.[193]

ART-A, through its agreements with consortium members, has built a Protected Commons, covering access to technology and improvements by the consortium members. The question is whether this should be expanded to include users of the technology, i.e., laboratories that use the technology in Africa. In other words, would laboratories then access methods through a Protected Commons license agreement rather than public domain information or an open source type license agreement? Given that laboratories as the users of the technology are unlikely to want to patent improvements to the technology and may also want to publish and freely use the data generated, it would seem that the open access model would be preferred. So the protected commons concept is perhaps better suited to

189 Creative commons [online] <http://creativecommons.org/licenses/by/2.5/> (Accessed on 1 July 2011).

190 Open Source Initiative [online]. <www.opensource.org/docs/definition.php> (Accessed on 1 July 2011).

191 GNU Operating System (2007). GNU General Public License. <http://www.gnu.org/licenses/gpl.html> (Accessed on 1 July 2011).

192 BIOS [online].< http://www.bios.net/daisy/bios/404.html> (Accessed on 1 July 2011).

193 Cambialabs [online].<http://www.cambia.org/daisy/cambialabs/3186.html> (Accessed on 1 July 2011).

consortium members developing technology but not for end users like clinical diagnostic laboratories.

### 5.5 Freedom to Operate

Given that ART-A has in a sense made a "generic" version of the current commercial HIVDR tests, it is as important to consider freedom to operate as it is to consider how to protect ART-A IP (or not). Here it is important to clarify the distinction between IP protection and the exploitation of IP. Intellectual property protection refers to the act of securing one's intellectual property to prevent unauthorised use of the IP by a third party. IP exploitation, on the other hand, takes place when one exercises their rights to use certain intellectual property. IP exploitation encompasses a wide range of activities that include technology transfer, research collaborations where protected inventions are incorporated into new products, processes and services, sale of IP and licensing and commercialisation. To be able to exploit intellectual property one needs freedom to operate (FTO), meaning that the new IP being developed will not infringe valid intellectual property rights of others. If it does then IP rights need to be obtained to ensure FTO, and these may often not be obtainable. Thus, a good understanding of the FTO is essential for technology development and transfer.

Planning for the exploitation of new IP is as much about forecasting future market developments and opportunities as it is about minimising risks and identifying the business model to be used as described above. Before exploiting IP, it is good practice to ensure that the new IP being developed will not infringe valid intellectual property rights of others. The purpose of an FTO search is to find relevant unexpired patents or patent applications that could become barriers to commercialise one's own IP in the countries targeted for the production, use and sale of the proposed technology product.[194] Patent infringement is costly, not only because of litigation, but also from a potential wasted technology development investment perspective. And therefore ideally, an FTO exercise should be conducted even before undertaking new research. In the case of the ART-A consortium this was not done but is investigated here.

An FTO analysis can also assess the limitations of existing patents that provide opportunity for creating new IP which works around the inventions claimed in the patents concerned. These limitations may be based on territory, scope of the patent or its duration.[195] IP owners make strategic decisions about the countries in which they will seek patent protection. This decision is largely influenced by the location of the main markets for the technology. It is often not worth patenting in countries where commercialisation is less likely and as a result, the IP that is patented elsewhere then becomes public domain information in countries where it is not patented. In these latter countries, no permission (or license) is needed from the patent owner to commercialise the product.[196] FTO analysis can also help to identify the need to invent around blocking patents and alert the consortium to cross-licensing or collaboration opportunities.

In respect of the duration of a patent, patent protection lasts 20 years from the date of filing a complete application, provided that patent renewal fees are maintained in the

194 Wolff, T. (2008); Biotechnology Intellectual Property Management. [Online] 2001.

195 Burrone, E. (n.d.).

196 Idem.

countries concerned for the duration of the patent's lifespan. After the expiry of the term of protection, a patented invention is considered to be in the public domain and may therefore be freely used by any other person.

The scope of a patent is limited by the specific claims listed in the patent and all aspects of an invention that are not covered by the claims are not considered to be patented.[197]

In the event that there are valid patents that prevent one from exploiting their intellectual property, there are options to consider in order to gain freedom to operate. Purchasing, cross-licensing or in-licensing the patent are the first option. To this end, the patent holder provides the authority to a third party to use the patented technology for specific functions, in specified markets and for a specified period of time. The feasibility of such an agreement will depend largely on the terms and conditions of the proposed license. This approach is often the simplest way of clearing the grounds for the commercialisation of a new technology or product.[198] A second, but potentially costly, alternative is to invent around the inhibiting patent. This solution is more viable when dealing with a process patent whereby a different process can be used to arrive at the same end-point. The third approach is the patent pool model discussed in Chapter 6 whereby two or more companies practicing related technologies put their patents in a pool to establish a clearinghouse for patent rights.

Patent protection if granted, is designed to provide the owner the right to exclude others from using the patented invention. Depending on the objectives of the IP owner, the intellectual property can be exploited for economic gain and/or social good. There are cases where an IP owner may wish not to patent a technology. Defensive publishing or technical disclosures have been used, which means the information is placed into the public domain thus preventing future patenting and in so doing, providing some degree of freedom to operate to all.[199] An important point when selecting to publish defensively is that the disclosure is best done in a well-recognized technical journal or other publication that is likely to be consulted by patent examiners checking literature when examining patent applications.[200] This will help to reduce the chances that nobody has the right to exclude other parties' use of the technology.

The relevance of conducting FTO analyzes in Africa where levels of patenting are low might be questioned, however with increasing evidence of more patents being filed in South Africa this cannot be neglected. For example non-resident direct patent filings in South Africa increased by 10.6% from 2004 to 2005.[201]

### 5.5.1 FTO and ART-A Technologies

FTO analysis when applied to ART-A is complex. With so many technologies being employed in the different steps,[202] simply trying to search for all possible patents that may be infringed is in this specific ART-A case is impractical. For this report we use as an example the DNA amplification and sequencing steps of HIV drug resistance methodology developed by ART-A. The same principles in establishing FTO for the other ART-A developed methods (e.g., dried

197 Idem.

198 Wolff, T. (2008).

199 Henkel, J. and Pangerl, S. (2007); Cogen, J. M. and Colson, T. M. (2001), pp. 40-46.

200 Wolff, T. (2008).

201 WIPO Patent Report 2007.

202 For a detailed description of the ART-A technologies developed see Chapter 2.

blood spot collection and viral load assays) will apply, but we use this example as it incorporates a number of technologies and is therefore more complex, giving insight into the different factors to be considered when doing an FTO analysis.

Initially, the steps involved need to be broken down into their constituent parts which in this case involves: extraction of nucleic acid from patient's blood or plasma sample; amplification of the relevant genes by PCR; and then sequencing of each of these PCR amplified products by DNA sequencing. One can then analyze all the equipment and reagents that are used in each step that could have IP rights attached. For this, the product information that comes with each reagent, component or instrument can be used. Usually, if there are rights attached to the use of a particular product then the package insert will specify this. Our analysis of all the product information supplied by manufacturers indicated the following:[203]

1. No apparent intellectual property rights were associated with the methods employed by ART-A for extraction and purification of nucleic acids from patient samples.
2. There were significant IP rights associated with the use of enzymes and methods of amplification, as well as the instruments used and methods of DNA sequencing. The list of products which have rights granted (or restrictions applied) that affect their use following purchase are show in Table 5.2.

**Table 5.2** ***Showing rights or restrictions attached to purchase of products required for ART-A technologies***

| Product | Manu-facturer | IP Rights attached with purchase | Summarised Description or Extract from Product Package insert[204] |
|---|---|---|---|
| Thermal Cycler Equipment | Applied Biosystems | None | "The thermal cycler is covered by US patent claims, and corresponding claims in their non-US counterparts. No right is conveyed expressly, by implication, or by estoppel under any other patent claim, such as claims to apparatus, reagents, kits, or methods such as 5′ nuclease methods." A contact address for purchasing licenses is supplied[205]. US patents are not listed. |
| Thermostable polymerase enzymes kit | Invitrogen | Limited use license under 5 categories:<br><br>Thermostable polymerases | With each limited use license contact details are provided for enquiries about purchasing a license to use this product or the technology embedded in it for any use other than for research use.<br><br>"Use of product covered by one or more of the following US patents and corresponding patent claims outside the |

[203] Our review was not exhaustive.

[204] The wording is extracted directly from the purchaser license information shown in product package inserts

[205] Applied Biosystems (2010).GeneAmp PCR System 2700 for amplification of nucleic acids. User Guide. <http://www3.appliedbiosystems.com/cms/groups/mcb_support/documents/generaldocuments/cms_041169.pdf> (Accessed 15 December 2010).

| | | | |
|---|---|---|---|
| | | | US: 5,789,224, 5,618,711, and 6,127,155. Purchase of product includes a limited, non-transferable immunity from suit under the foregoing patent claims for using only this amount of product for the purchaser's own internal research. No right under any other patent claim, no right to perform any patented method, and no right to perform commercial services of any kind, including without limitation reporting the results of purchaser's activities for a fee or other commercial consideration, is conveyed expressly, by implication, or by estoppel. This product is for research use only. Diagnostic uses under Roche patents require a separate license from Roche. " |
| | | Invitrogen technology | "The purchase of this product conveys to the buyer the non-transferable right to use the purchased amount of the product and components of the product in research conducted by the buyer (whether the buyer is an academic or for-profit entity). The buyer cannot sell or otherwise transfer (a) this product (b) its components or (c) materials made using this product or its components to a third party or otherwise use this product or its components or materials made using this product or its components for Commercial Purposes. The buyer may transfer information or materials made through the use of this product to a scientific collaborator, provided that such transfer is not for any Commercial Purpose, and that such collaborator agrees in writing (a) not to transfer such materials to any third party, and (b) to use such transferred materials and/or information solely for research and not for Commercial Purposes. Commercial Purposes means any activity by a party for consideration and may include, but is not limited to: (1) use of the product or its components in manufacturing; (2) use of |

[206] Based on this it is not clear whether contract research at a university is excluded.

| | | | |
|---|---|---|---|
| | | | the product or its components to provide a service, information, or data;[206] (3) use of the product or its components for therapeutic, diagnostic or prophylactic purposes; or (4) resale of the product or its components, whether or not such product or its components are resold for use in research. For products that are subject to multiple limited use label licenses, the terms of the most restrictive limited use label license shall apply. Life Technologies Corporation will not assert a claim against the buyer of infringement of patents owned or controlled by Life Technologies Corporation which cover this product based upon the manufacture, use or sale of a therapeutic, clinical diagnostic, vaccine or prophylactic product developed in research by the buyer in which this product or its components was employed, provided that neither this product nor any of its components was used in the manufacture of such product. " |
| | | Platinum® products | "Licensed to Invitrogen Corporation, under U.S. Patent Nos. 5,338, 671; 5,587,287 and foreign equivalents for use in research only." |
| | | Thermostable DNA Polymerase Blend | "Product is subject of U.S. Patent No. 5,436,149 and corresponding foreign patents licensed by Takara Corporation to Invitrogen. This product may used only for research purposes and may not be resold or used for therapeutic purposes." |
| | | One-Step RT-PCR | "Product is sold under license from bioMerieux under US patent 5,654,143, US Patent 5,817,465, and/or any patent issuing from a reissue thereof and their foreign counterparts, and is for Research Use Only." |
| Cycle sequencing of genes kit | Applied Biosystems | | "A license under the process claims of U.S. Patents 5,332,666 and 5,821,058 or their foreign counterpart claims, has an up-front fee component and a running-royalty |

| | | | |
|---|---|---|---|
| | | | component. The purchase price of BigDye® Terminator v3.1 Cycle Sequencing Kit includes limited, non-transferable rights under the running-royalty component to use only this amount of the product to practice the DNA sequence and fragment analysis processes described in said patents when this product is used in conjunction with an Authorized DNA sequence analysis instrument whose use is covered under the up-front fee component of these patents. No other rights are granted expressly, by implication, or by estoppel, or under any other patent rights owned or licensable by Applied Biosystems."[207] |
| DNA purification kit used in sequencing | Qiagen | Limited | "The kit may be used solely in accordance with the Handbook and for use with components contained in the Kit only. Qiagen grants no license under any of its intellectual property to use or incorporate the enclosed components of this Kit with any components not included within this Kit except as described in the Handbook and additional protocols.<br>Makes no warranty that this kit does not infringe the rights of third parties.<br>The kit and its components are licensed for one-time use and may not be reused, refurbished or re-sold." |

Taking all of these IP rights associated with these methods into consideration, one can generate a list of patents that are applicable to use of these reagents. For a laboratory operating in Africa these patents would then need to be searched on patent databases to see if they have registered foreign equivalents in the relevant African territories. If they do and these registered foreign patents are still valid, then the impact of these patents on the ART-A methods would need to be assessed by reviewing the claims. There is the added factor that in the case of ART-A technologies (and most other IVD technologies), the components for the assays are manufactured by companies in the US and so even if they are not patented in Africa they are still subject to patents in the country of manufacture. As outlined above, the issue of patents may in fact be the more minor issue since the product package inserts bind users by contracts and licenses and it is through the terms of these requirements that use is restricted rather than through patents.

[207] <https://products.invitrogen.com/ivgn/product/12574026> (Accessed 15 Dec 2010).

We performed a preliminary assessment[208] of the patents highlighted in the product package inserts to see firstly if any foreign equivalents had been filed in Africa. The options for patent searching and different databases both public and private that can be used are well described by Verbeure and colleagues.[209] Various patent offices do provide this type of search service for a fee but it is expensive and therefore beyond the capabilities of many laboratories. One of the main problems with searching for patent filings in Africa that are the "foreign equivalents" of US or European patents is that most African countries where ART-A technology is to be implemented do not provide free online patent search facilities. Even the South African Companies and Intellectual Property Registration Office (CIPRO), which does provide a search engine,[210] can only search on patent title or inventor name. Recently however, WIPO has introduced a new search tool that allows South African and ARIPO patent collections (amongst others) to be searched with limited search terms[211] and the Cambia Patent Lens Search Tool also provides a good free search tool in this area.

Our search of the ten US patents that were listed in package inserts of commercial products used in ART-A protocols showed highly variable sizes in patent families ranging from 7 to 334 documents per US patent. Despite this, only five patents had been filed in Africa (See table 8.3) all of which were filed in South Africa, and all were now "dead patents"[212] meaning they no longer had any rights attached, due to the fact they were out of term, or for other reasons not easily ascertained.

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208 For this we initially searched the European patent database resource Espacenet <http://ep.espacenet.com/> using the US publication number, then looked at all patents in the patent family to see how many were filed in Africa. We confirmed patent searches using the new WIPO patent search tool. <http://www.wipo.int/patentscope/search/en/search.jsf> (Accessed on 1 July 2011).

209 Verbeure, B., Matthijs, G. and Van Overwalle, G. (2006), pp. 26-33.

210 Companies and Intellectual Property Commission. <http://patentsearch.cipro.gov.za/> (Accessed on 1 July 2011).

211 WIPO. Patent scope [online].<http://www.wipo.int/patentscope/search/en/search.jsf> (Accessed on 1 July 2011).

212 This is terminology used to describe patents that are "abandoned, withdrawn or deemed to be withdrawn, revoked or out of term" by Huys, I., Berthels, N., Matthijs, G. and Van Overwalle, G. 2009. Legal uncertainty in the area of genetic diagnostic testing. *Nat Biotechnol,* 27**,** pp. 903-909.

**Table 5.3:** ***List of US Patents identified on Product Package Inserts and their Corresponding African Filings***

| US Patent # | Patent Title | Patent Family Size[213] (IPC) | Identified African Patent Publication Number/Publication Date[214] |
|---|---|---|---|
| 5,789,224 | Recombinant expression vectors and purification methods for thermus thermophilus DNA polymerase | 310 (C12N9/12) | ZA8900262 (A) / 1990-09-26 Expired<br>ZA8706216 (A) / 1989-04-26 Expired<br>ZA8700152 (A) / 1988-09-28 Expired<br>ZA8602335 (A) / 1987-11-25 Expired<br>ZA8602334 (A) / 1987-11-25 Expired |
| 5,618,711 | Recombinant expression vectors and purification methods for Thermus thermophilus DNA polymerase | 334 (C12N9/12) | As above |
| 6,127,155 | Stabilized thermostable nucleic acid polymerase compositions containing non-ionic polymeric detergents | 334(C12N15/70;C12N9/12;C12P19/34) | As above |
| 5,338,671 | DNA amplification with thermostable DNA polymerase and polymerase inhibiting antibody | 7 (C07K16/40;C N12N15/09;C 12N9/12) | None |
| 5,587,287 | Thermostable polymerase specific antibody-containing DNA amplification composition and kit | 7 (C07K16/40;C 12N15/09;C12 N9/12) | None |
| 5,436,149 | Thermostable DNA polymerase with enhanced thermostability and enhanced length and efficiency of primer extension | 19 (C07H21/04;C 12N1/21;C12 N15/09) | None |
| 5,654,143 | RNA amplification method requiring only one manipulation step | 8(C12Q1/68;C 12P19/34) | None |

213 This indicates the number of patent documents in the patent family based on the US patent. According to Espacenet® a patent family "is defined as comprising all the documents sharing directly or indirectly (e.g. via a third document) at least one priority. This includes all the patent documents resulting from a patent application submitted as a first filing with a patent office and from the same patent application filed within the priority year with a patent office in any other country". <http://ep.espacenet.com/help?topic=patentfamily&locale=en_EP&method=handleHelpTopic> (Accessed on 1 July 2011).

214 Looking only at South Africa (ZA), Uganda (UG) and also ARIPO(AP) and OAPI (OA).

| | | | |
|---|---|---|---|
| 5,817,465 | RNA amplification method requiring only one manipulation step | 8(C12Q168;C12P19/34) | None |
| 5,332,666 | Method, system and reagents for DNA sequencing | 36(C07D311/82;C07D311/84;C07D311/86) | None |
| 5,821,058 | Automated DNA sequencing technique | 18(C12Q1/68;G01N27/447;C12Q1/68) | None |

This preliminary search suggests that for the ART-A HIV drug resistance protocol, from extracting DNA to generating sequence, does not infringe any patents filed in the territory of Africa, with respect to disclosures made by product manufactures of the component reagents.We were also interested in how possible HIV gene patents or patents on primer sequences may affect ART-A. Again to search for all patents that encode HIV primer sequences would be extremely tedious, although we did some preliminary analysis as already described searching primer sequences using Cambia's Patentlens Sequence Search Facility).[215] So we used the disclosures on patent sequences from current commercial assays to determine if any primer or HIV gene sequences were being infringed. Preliminary analysis suggested not.[216]

So it is unlikely that patent protection in Africa that would cause ART-A to infringe on patents. However, it is the fact that most component parts are manufactured in the US and that these US suppliers attach contractual limitations acquired on purchase, in terms and conditions of sale, that would create barriers to use (as detailed in Table 5.2). These companies state in their terms and conditions of sale that for commercial and diagnostic use licenses are required. So the key question that requires further research is to investigate the terms and conditions of such licenses and how they would affect laboratories' ability to perform testing.

Another option is to look at component products that could be used in the ART-A assays that have less IP restrictions or suppliers that have less restrictions in their terms and conditions of sale. Finally, the terms of commercial use versus research use need to be better defined and understood. Is the use of these products in a diagnostics lab that is providing a fee for service or charging for the test (to governments or private patients) regarded as commercial use? Even in the US, clinical laboratories use RUO reagents in LDTs, so are they being charged license fees in addition to use RUO reagents in their LDT? This likely involves engaging with the companies involved in manufacture of the component parts to understand their definition and also to see what kind of licensing terms might be offered to see the effect on costs and potential access.

### 5.5.2 FTO and Gene Patents in Africa

Patents on genes have been shown to prevent pathology laboratories in the US from performing certain genetic tests.[217] To check this in terms of African countries we also

[215] Patent lens [online].<http://www.patentlens.net/sequence/blast/blast.html> (Accessed on 1 July 2011).

[216] This was discussed in more detail above in section 8.4.1.

[217] Cho, M. K., Illangasekare, S., Weaver, M. A., Leonard, D. G. & Merz, J. F. ( 2003), pp. 3-8.

conducted a preliminary search of the "blocking" patents covering genes for diagnosis of cystic fibrosis and factor V leiden that were identified by Huys et al.[218] We found that none of these patents had equivalent filings in any African countries. It would therefore appear that patenting of genes in African countries is not currently a block to diagnostic testing.[219] This could actually be an opportunity for African countries to perform genetic diagnostics testing unencumbered by patent constraints.

Even the highly contentious BRCA patents[220] held by Myriad Genetics and filed in US and Europe do not appear to have African filings.[221] This would imply that despite the issues with gene patents in the developing world these are not an issue currently in preventing access to genetic testing in Africa due to the patents on these genes simply not being filed in Africa.

But it already has been identified that most of the component reagents for the ART-A tests are manufactured in territories where patent rights are attached. We recommend that more comprehensive research is required to ascertain exactly what genes have been filed for patent in African countries, particularly if any on important diseases, before making final conclusions. In addition, this situation is likely to change as Africa markets for genetic testing grow.

### 5.6 Policies Promoting or Restricting ART-A FTO

Intellectual property law has become an integral part of trade and development policy. Annex V deals extensively with national and regional policies and legislation that govern intellectual property issues in Uganda and South Africa specifically. References to the TRIPS Agreement made in the same chapter demonstrate how the international intellectual property system is designed to facilitate the role of national and regional legal IP frameworks.[222] The international agreements and treaties are intended to give regional and national IP bodies greater autonomy to develop, interpret and implement IP laws based on the international frameworks provided. Restrictions and liberties provided in the national and regional laws therefore determine the freedom to operate within a given jurisdiction. Today, intellectual property products are able to reach a greater number of international communities with speed resulting in commerce at a global scale. National and regional intellectual property laws need to have global reach, and respond quickly to new problems and new technologies.[223]

It could be argued that the mere existence of IP legislation to a certain degree limits freedom to operate for the simple reason that IP protection excludes unauthorized users from exploiting a given technology. However, as discussed in the previous section, there are

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218 Huys, I., Berthels, N., Matthijs, G. and Van Overwalle, G. (2009), pp. 903-909.

219 Discussions with a number of pathology laboratories in South Africa (need to also check on Uganda) suggest that when laboratories engage in offering genetic diagnostic testing including HIV resistance tests these laboratories do not investigate whether they are infringing patents. The reason for this is either simple ignorance of the fact that they may need to conduct a freedom to operate analysis or that they do not have the resources to investigate such issues and would rather wait until they receive cease and desist letters from the patent holder, which is rarely or never.

220 Marshall, E. 2010. Patents. Cancer gene patents ruled invalid. *Science,* 328, p. 153.

221 We performed similar searches on these patents' African counterparts and none were found.

222 Dinwoodie, G. (2007).

223 Ibid.

options and alternatives to consider to obtain freedom to operate. Overly restricted access to intellectual property does more than inhibit freedom to operate. It increases the cost associated with transacting intellectual property rights, especially in cases where there are broadly or poorly defined claims in individual patents or products involve technologies claimed by multiple IPR holders.[224] Confusion over the proliferation of nascent IP policies in many countries, such as Uganda and South Africa, insufficient policy coordination, and the lack of education and experience among researchers and administrators in dealing with the international dimension of patent issues are also a problem.

Developing country inventors need better information and better access to technologies and therefore would be better served by mechanisms that reduce IPR-induced transaction costs. One such way to do this might be to standardise processes for obtaining licenses or license terms themselves, although this may not actually be practical. Such transaction costs include:[225]

a. Identifying who has which rights to which technologies
b. Conducting objective valuations of IPRs and designing compensation schemes
d. Managing flows of royalty payments
e. Enforcing contracts

Education in IP practical policy and legal issues should be emphasised in developing countries in order that they may know when and where IPRs are a real constraint and therefore, how to obtain favourable conditions for using existing technologies. Of special importance is prioritising where and when to build which specific capacities so that resources are not wasted.

### 5.7 How to Handle Publication vs. Patenting in the Consortium

The tensions between whether to publish or to patent continue to concern academic institutions, especially those that have an entrenched history of publishing academic work for the purposes of knowledge dissemination and to feature high quality research. The issue is not whether to patent or to publish, but how to accomplish both when in a consortium of academic and private sector entities. The publication of research results in peer-reviewed journals and oral presentations at conferences are the major ways in which academic researchers inform the scientific community of their new discoveries. The academic community makes wide use of the Scientific Citation Index for scientific impact of a scientist's work.[226] Identification of an invention within research results and the subsequent decision to file a patent application can delay the publication of research results, and therefore, academics cannot immediately announce new results without some loss of patent rights. The US patent system allows an inventor a year's grace period to file a patent following public disclosure of patentable intellectual property while the rest of the world requires that a patent (provisional or other) is filed prior to public disclosure and does not offer the grace period.[227]

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224 Zilberman, G.G. and Zilberman, D. (2001).

225 Gregory, G., Bennett, A., Wright, B. and Zilberman, D. (2001), pp. 12-30.

226 Quaite-Randall, E (n.d).

227 Mossinghof, G.J. and Ku, V.S., World Patent System Circa 20XX, AD. [Online] 1998. <http://www.ipmall.org/hosted_resources/IDEA/38_IDEA/38-4_IDEA_529_Mossinghoff.pdf> (Cited: 07 October 2010); Patent. [Online]. <http://www.fact-index.com/p/pa/patent.html> (Cited: 07 October 2010).

Some countries provide for a grace period under strictly limited conditions, e.g., Australia, Brazil, Canada, Japan, Malaysia, Mexico, South Korea.

Fortunately, the academic world is changing and the culture of 'patent and prosper' as opposed to 'publish or perish' has growing acceptance among researchers and institutions alike.[228] Financial pressures experienced by institutions have forced them to consider other means of increasing revenues, including exploring opportunities to exploit the intellectual capital that exists within R&D institutions. Some academic institutions have produced blockbuster patents that have resulted in millions of royalty and licensing dollars. However, such fortunes are few and far between. Thus said, there always remains the hope of being the source of the next technology hit.

When managing new IP, institutions need to decide whether or not to patent. There are several valid reasons why one may decide not to patent. First of all, the cost of patenting is high in terms of legal and filing fees, significant time and effort is required from the inventor to complete claims and so on, such that going through the process for a small innovation may not be worthwhile. Second, patenting requires that the inventor disclose the discovery in detail. This is an indication to competitors of a new invention while at the same time the patent enables imitators to invent around the patent.[229] Both these factors have commercial implications and need to be carefully considered if market leadership is the goal.

There is also a risk associated with not patenting or disclosing. If at a later stage another inventor patents the same invention, this may preclude the first inventor from practising their own intellectual property.

The tensions between patenting and publishing are less about one option over the other than about the timing of the IP disclosure. Often the prospect of new IP is raised when an academic is about to submit a paper for publication or present at a conference. The result is time pressure where decisions and actions need to be carried out quickly.

In the same way that consortiums manage the research process in a proactive manner, it is necessary to manage IP proactively. Scientific review meetings should include a discussion on what new IP will be generated and at what stage of the research it is expected. This way, it is possible to plan ahead as to how that IP will be managed. After a researcher has conducted a literature review on their chosen topic – which review should also include an IP search – they should know what is novel about their work and, consequently, be able to speculate what new IP is expected from that research. A system of tracking and recording IP emanating from research work is important and communicating to researchers the importance of identifying and reporting new IP is essential.

### 5.8 Strategic Options for Ensuring Access to ART-A Technology

Different options are possible for ART-A to ensure that its technology is widely used and employed for its purpose of providing more affordable HIV drug resistance testing in Africa.[230] Each one of these questions has different issues that need to be considered from both IP and regulatory perspectives. This will influence the final decision taken by ART-A to ensure that an

[228] Schachman, H. K. (2006), pp. 6889-6903.

[229] Vincenzo Denicolò, V. and Franzoni, L.A. (2002).

[230] There may be more options available to the consortium but for the purposes of this analysis we limit it to the most obvious strategies in order to provide a reasonable analysis of how IP protection and IP rights can enhance or limit these options.

option would be viable. The IP issues *per se* do not necessarily drive this decision but play a role in deciding on the best option.

Key questions that would need to be addressed by the ART-A consortium in relation to making choices around IP are:

1. How will the technology be disseminated as widely as possible to the target market?
2. What will be the role of ART-A consortium in determining uptake and/or what other parties would drive this?
3. To what extent will African laboratories seek the use of the technology or will other entities seek the technology on their behalf?
4. What is the business model for technology transfer?

### 5.8.1 Open Access – Public Domain with Open Source Software

This option would allow the ART-A consortium to simply publish the methods developed in scientific journals and/or provide more detailed protocol information through a website where all protocols can be downloaded for free or at a nominal cost, including the software that ART-A developed for DNA sequence analysis. This would include providing details of the specific DNA primers used, amplification and detection methods in sufficient detail, even potentially in the form of standard operating procedures available as a separate download from a dedicated site with limited restrictions (like the requirement for registration and provision of some details before downloading could proceed). The methods would be provided without ART-A retaining any IP ownership (public domain).

Open source access to the ART-A software would allow free access but with license conditions ensuring improvements are shared. This open access model is feasible since all of the components (e.g., primers, enzymes, and other reagents) that make up the methods required to conduct both viral load and drug resistance testing assays can be obtained from commercial suppliers.

The software lends itself especially well to an open source license format and could be provided under an open source license for free access (e.g., GNU General Public License[231]), whereby the licensee agrees that the software remains publicly accessible, to prevent appropriation of the software.[232] Other developers could improve, share improvements and transfer the software to others on the same terms. It is important to note that there are a range of open source licenses to choose from depending on how permissive or restrictive the use of software is intended. However, in the ART-A case, because the component software used to build the ART-A software is all based on GPL-licensed software, it would have to be licensed on the same terms.

The main issue with this type of approach in the case of ART-A is that the burden of analysing and acquiring freedom to operate falls onto individual laboratories. They would need to ensure that the ART-A methods they are using do not infringe any patents in their territories and then negotiate licenses if necessary. Most laboratories do not possess the necessary skill to perform such freedom to operate analysis, and in many cases don't deem it necessary due to perceived or real low risk of infringement and minimal benefit of doing so.

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[231] GNU Operating system (2007). GNU General Public License. <http://www.gnu.org/licenses/gpl.html> (Accessed on 1 July 2011).

[232] Boettiger S. and Chi-Ham, C. (2007).

This may in fact be the case where the risk of a laboratory being sued for infringement is lower than the cost of doing an FTP analysis and hence taking the risk is a better option.

One could argue that the WHO HIV Drug Resistance Program has taken this approach by simply making protocols available on a website for download, but they have not addressed any FTO issues in their program.[233]

### 5.8.2 Product Bundling Under License from Component Manufacturers

Another option would be to publish and make methods and software accessible as described, but to overcome the key problem in Africa of inconsistency in supply from different reagent suppliers. All the necessary components required for the HIV drug resistance test could be bundled into a single package (also called a "bundle"). This bundle of all the components could then be sourced from a single reliable supplier in the relevant country. This should improve supply of all test components and offer an opportunity for quality control of all the input RUO components of the assay, i.e., a batch of reagents could be centrally tested before distribution conferring batch control of all components. It would however require that ART-A obtains the interest of a third-party "bundler" (manufacturer or distributor) to do this. It could however provide an opportunity for an African enterprise to source and package the components.

Such an approach has been used for the supply of PCR diagnostic reagents for early infant HIV diagnosis by Roche Diagnostics and has shown to improve the access to testing.[234] This involved packaging of all components required for an HIV DNA PCR test (used for early infant HIV diagnosis in Africa) into one "bundle" and supplying this bundle directly to labs doing the testing. The advantages of bundling are the purchasing power the "bundler" would have with individual reagent suppliers, as well as consistency of reagents used. Overall cost savings could be passed on to the testing laboratory, or used to recover costs associated with "bundling".

This "bundling" approach however has a serious added complication as obtaining permission from the individual reagent suppliers to bundle and resell their products would need to be addressed. But since it would only need to be negotiated once between the "bundler" and different suppliers, it may be worth pursuing. Reagent suppliers in some cases specifically state that "*the purchase of this product conveys to the buyer the non-transferable right to use the purchased amount of the product and components of the product in research conducted by the buyer (whether the buyer is an academic or for-profit entity). The buyer cannot sell or otherwise transfer (a) this product (b) its components or (c) materials made using this product or its components to a third party or otherwise use this product or its components or materials made using this product or its components for Commercial Purposes*".[235] In fact, some of these conditions are imposed by regulatory requirements in country of manufacture.[236] These limited use and non-transferable rights conditions could directly restrict this option.

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233 World Health Organization (2009).HIV drug resistance laboratory training package. <http://www.who.int/hiv/pub/drugresistance/lab_training/en/index.html> (Accessed on 1 July 2011).

234 <www.aids2008.org/Pag/ppt/MOSAT0803.ppt.andwww.who.int/hiv/pub/meetingreports/EID_program_scale_up_SEssajee.ppt> (Accessed on 1 July 2011).

235 This is terminology used in the package insert for the thermostable enzymes from a commercial supplier. <https://products.invitrogen.com/ivgn/product/12574026> (Accessed on 1 July 2011).

236 World Health Organisation (2003). Medical Device regulations: global overview and guiding principles.

There may be the option to negotiate different terms with the commercial component supplier, however there are also a number of potential regulatory issues (as discussed in Section 5.2.2).

Finally, the question with this bundle approach is whether ART-A would license any IP to the "bundler" for a competitive advantage assuming there is licensable IP, or whether the "bundler" would rely on specific agreements with each reagent supplier to gain a competitive advantage. Or perhaps exclusive distribution rights on a territorial basis could be granted to "bundler" by ART-A or reagent suppliers. In addition, the "bundler" could be given a license to use the ART-A trademark improving brand recognition and acceptance of the bundled product.

### 5.8.3 Commercial Licensing of ART-A Trademark

As discussed in Section 5.5.3, the ART-A logo and name could be registered as trademark in the relevant countries where the assay likely would be used. The consortium could then license the use of the trademark to a commercial manufacturer or "bundler" of the assay. The consortium could itself use the trademark as a way of identifying the "bundled" product if it decided to do the "bundling" itself. The value of an ART-A trademark is not to be underestimated given the publication track record of the consortium and the expertise of the group that would likely also be associated with the HIV drug resistance testing products that are identified by the trademark. This would also offer value to a company that would take on the "bundling" role and could be used as a means of marketing and building on the already established affordable drug resistance brand, which has associated peer review publications that are known to the HIV drug resistance testing customer base. It would also prevent others from simply using the brand and referring to ART-A without being licensed to do so. Licensing of the trademark is a way for ART-A consortium to potentially derive income to support training activities.

### 5.8.4 Commercial Licensing of Patented Technology

This option is dependent on ART-A securing registrable IP in the form of patents. This would allow ART-A to provide the methods under a license to a commercial kit manufacturer who could assemble a kit and validate it. The current ART-A consortium arrangements (defined by the grant agreement) do not allow for licensing of IP for commercial use in the territory of Africa, but do allow for licensing of the technology for commercial use elsewhere, though with the possibility of being re-negotiated.

The problem with this patent licensing approach is that is it likely the commercial manufacturer will prefer an exclusive license to methods that are not in the public domain to provide a competitive advantage and prevent competition from "generic" kit manufacturers or other labs using laboratory developed tests (LDTs). And once methods are in the public domain this is not possible. This appears to be counter to the ART-A consortium aim, as required by the funder, which is to publish information and provide wide access to the information. If provisional patents were filed prior to publication, but did not prevent eventual publication, then at least ART-A could explore this option and by having the patent it would allow for the consortium to explore a number of options for open access. Eventually, a license agreement could be achieved that reaches a suitable compromise to encourage use in the

developed and developing world. Socially responsible licensing options[237] can provide for this, and there are many examples now where licenses can provide for royalty-free use of products in the developing world.[238] The advantage of the ART-A consortium owning the patent is that it could negotiate the terms that support access in Africa.

## 5.9 IP Management Tools

All members of the ART-A consortium need to be aware of a range of issues that can impact the project and that are relevant to management of IP. Table 5.4 and Table 5.5 below provide an IP management and exploitation checklist for ART-A The purpose of these checklists is to ensure that all aspects for disclosure, protection and exploitation of IP are covered and not neglected, and provide a guide for development of the consortium IP strategy. For each category that deals with an aspect of IP,criticial issues are described as well as potential pros and cons of different types of IP exploitation tools that can be used. The purpose of an IP strategy is to encourage research excellence and provide incentives for the development of IP and the exploitation of resulting technologies for the best interests of the collaboration. Importantly, such a checklist and the resulting responsibilities would need to be managed, preferably by the co-ordinating leader of the consortium, and could also be used to educate all consortium members.

An additional area of focus is direct technology transfer activities such as ongoing training programs with laboratories in Africa. This provides an excellent way to ensure that the technology is adopted and that expertise is developed in performing the assays. This has been an integral part of the ART-A program and should not be underestimated as a way to disperse knowledge gained by the consortium for the benefit of the laboratories and patients.

All these factors should also be considered in relation to the timeframe of R&D, from the initial concept of the project, to awarding of funding, to technology development, to use by testing laboratories and use of the data by doctors and patients. This is represented in Table 5.5. Considering all critical factors and components in relation to the timeframe and in conjunction with the checklist helps to identify factors that need to be considered in decision-making. One could segment this further to cover more defined steps in the technology development timeframe for a more detailed analysis. For simplification, here we have looked at these five stages of development. Some aspects will need to be considered throughout the process whilst others will only need attention at different phases, but this provides an overall idea of issues involved that need to be considered.

[237] As discussed in Chapter 6.

[238] Brewster, A. L., Hansen, S. A. and Chapman, A. R. (2007).

**Table 5.4** ***IP Management Checklist***

| Categories | Description |
|---|---|
| **Consortium Agreements** | • Consortium members need to be cognizant of the need to use Non-disclosure and Material Transfer Agreements and Research Contracts as required<br>• A document management system is needed to ensure that all members of the consortium are aware of existing contracts and are able to access them |
| **Publishing** | • Scientists are expected to publish and present their results and the consortium should not restrict this freedom. However, scientists must disclose any potential IP before it is published or presented in public<br>• Further, scientists need to be aware of any restrictions that collaboration agreements may place on publishing<br>• Material planned for publishing needs prior approval |
| **Trade-Secrets and Know-How** | • Where it is decided that certain IP should be kept secret, measures to ensure that secrecy is maintained need to be explored and established, but as discussed probably not a good strategy for ART-A<br>• Know-how is an important component of technology transfer. Measures need to be taken to identify and capture existing know-how |
| **Benefit Sharing** | • Clarity is required on how commercial returns resulting from the exploitation of IP developed by the consortium will be shared amongst members<br>• Beneficiaries need to be identified, preferably before money flows in from commercialization |
| **Dispute Resolution** | • A process for resolving disputes is normally outlined in a collaboration agreement. A similar process can be used to resolve IP related disputes |
| **Accountability** | • Each collaboration members needs to be aware of what they are accountable for in respect to managing consortium IP |
| **Compatibility** | • Most academic and certainly private sector institutions have IP policies. Consortium conditions with respect to managing IP need to take these policies into consideration. |

**Table 5.5** ***IP Exploitation Options***

| Exploitation Options | Pros | Cons |
|---|---|---|
| Publication | • Peer reviewed, provides scientific credibility, assists in awareness, branding and eventual trademarking | • Becomes public domain information and can be "hi-jacked" by third parties who can potentially claim IP rights to improvements |
| Open Source | • Ideal for software<br>• Allows for complete disclosure of info to users but with potential for sharing of improvements amongst all users<br>• Improved wider access and awareness | • Limited protection and can affect ability to patent in, for example, US |
| Protected Commons | • Provides a way for consortium to protect technology and any improvements particularly at early stages of development and particularly within the R&D team | • Not suitable for the end users, in this case laboratories who are more interested in using the technology then improving it<br>• Can be impractical to manage if many parties involved |
| Trademarking | • Allows brand recognition and licensing options for the consortium technologies without need for patenting | • Requires registration in each country where trademark protection is required with associated cost<br>• Requires prosecution in event of trademark infringement |
| Patenting | • Allows consortium to control licensing objectives | • Costly and potentially not relevant due to the lack of patentable ART-A inventions<br>• Also requires active enforcement in case of infringement |
| Trade- secrets | • Not appropriate for this consortium | • Not easily kept and defeats the object of consortium to spread knowledge to users |
| Direct Technology transfer | • Will improve success of adoption of technology<br>• Effective in encouraging technology utilisation | • Most likely requires on-site training and is therefore costly and requires on-going support from the consortium in terms of funding and expertise |

**Table 5.6** ***Different aspects to consider when assessing ART-A IP options at different Phases of Technology Development***

| Aspect | Pre-Grant Award | Grant Award and Initiation of R&D | Period from Start to Completion of Research Phase | Validation Assays by User Laboratories or Commercial Kit Manufacturers | End Usage by Laboratories for clinical IVD use |
|---|---|---|---|---|---|
| Research Materials | | MTA for clinical samples and protocols that are exchanged | Winding up of MTAs or extension | MOU for evaluation purposes | |
| Research Actors | NDA's<br>Consortium Agreements<br>FTO analysis<br>Defining and deciding on background IP to be brought into consortium | Consortium Agreements | Identifying inventions<br>Determining Ownership of Inventions | License Agreements<br>Different types<br>Humanitarian Use<br>Research Use<br>Differential roylaties for different territories | Managing licensing agreement royalties |
| IP Instruments (Inter-national or National) | Free Patent Search Tools (for FTO) | | Determining whether to patent and where<br>Provisional Patents<br>PCT Patents<br>Trademarks | National Territory patents<br>Open Source licenses<br>Patent Pools<br>Trademarks | National Patents (Territory Specific)<br>Open Source licenses<br>Trademarks |
| Institu-tional Actors | Grant Applications<br>Institutional approval letters of support | NWO Funding Agreements.<br>South African Intellectual Property Rights from Publically Funded Research Act. | University and Institute IP Policies | | TRIPS |
| Options to Protect IP or not | List Background IP | Confirm and agree on background IP to be included or excluded | Decided whether to provisionally patent or not or what other strategy to use | Determine whether to go to PCT | Determine whether to pursue national filings |

| | | | | | |
|---|---|---|---|---|---|
| Costs of IP protect-ion and manage-ment | Not applicable unless need to protect background IP | Not applicable at this stage | Low | Medium (Provisional and PCT patenting steps) | High (National Phase Patenting) depending on territories filed in |

### 5.9.1 Research Materials

These are the materials that are exchanged between consortium members under MTAs to allow for the research to be conducted. In the ART-A research consortium materials that were exchanged between parties were HIV patient blood samples used to test for HIV drug resistance and specific protocols for DNA extraction and sequencing. It is worth mentioning here that one should also consider the use of genetic resources and how this could impact on the Convention for Biological Diversity (CBD).[239] Our review of the CBD showed that the CBD focuses on biological diversity and genetic resources pertaining to flora and fauna. There has been some research as to whether the CBD should be expanded to include those human genetic resources, enabling research subjects to claim a share of the benefits to be negotiated on a case-by-case basis.[240] This research concludes that human genetic resources should not be included. It argues that there are already systems that function in the healthcare industry providing "fair exchange" to research subjects and no commercial benefit is being derived from the use of human biological material. Whilst this is arguable, it is also important that ethical approval be obtained as part of the requirements for research using human blood samples.

### 5.9.2 Research Actors

These are the institutional (public) and corporate (private) research entities involved together with their staff and where applicable students. Each of these have their own policies regarding IP and procedures for recognising and rewarding inventors in their employ, which need to be considered (and has been discussed in Section 4).

### 5.9.3 IP Instruments

These could be international or national IP instruments and focuses on patents and trademarks (but includes other forms of protection already mentioned). Patents include: provisional patents, PCT patents,and national territory patent filings. Other instruments would include national policies regarding publicly funded research and more global agreements such as TRIPS.

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239 Convention on Biological Diversity [online]. <http://www.cbd.int/> (Accessed on 1 July 2011).

240 Schroeder, D. & Lasen-Diaz, C. (2006), pp. 135-143.

### 5.9.4 Institutional Actors

These would be at a higher level than the research actors and would include the funding organisations that have their own policies around financing, funding, and reporting.

### 5.9.5 IP Options

This essentially described the routes taken at each stage, i.e., these include filing patents, providing material under open source licenses, and many different licensing options as well as public disclosures.

### 5.9.6 Costs of IP Protection and Management

Importantly, the costs of IP protection and management need to be considered, as at different points in the R&D cycle costs will be incurred that can differ radically and therefore require budgetary planning. We have ranked these as low, medium and high as costs tend to escalate over the course of IP protection time. In particular, patent costs escalate as one enters national filings.

## 5.10 Key Observations from Analysis of ART-A IP Environment

*The need for FTO analysis prior to technology development*
A key observation, that could only be fully understood by actually doing the preliminary FTO analysis, is that FTO analysis should ideally be done prior to, or at very least, in parallel with technology development. A good understanding of FTO can indicate where consortium research teams need to invent around existing patents rather than finding that developed technology needs then to be re-engineered later to get around IP rights associated with the technology. Whilst FTO analysis is time consuming and demands significant resources and expertise, it is often neglected. PPPs that seek research funding for technology development are often focused on the technology and do not have resources to do proper FTO analysis that can inform the research path to be taken. The role of TTOs in assisting research consortiums to do FTO analysis cannot be overemphasised and clearly capacity in Africa needs to be developed to support this. Improvements are required in the free patent search databases to enable more thorough and complex searches for FTO analysis. Additionally, a proper analysis of rights conferred to users of products purchased needed to be done. i.e., what rights to use are conferred by purchase. This was highlighted as a potential issue that ideally needs to be done prior to technology development.

In the case of ART-A, a complete FTO analysis prior to technology development would have suggested that sourcing critical reagents from territories where patents governing their manufacture and sale do not apply, and would have greatly enhanced the immediate and future FTO prospects. This would also mean that the ART-A consortium would have been able to validate assays with these unrestricted components. Selection of reagents that had less restrictive patent or other rights attached would also be useful. However, one thing that is not clear is whether in fact US manufacturers would enforce IP rights for HIV diagnostic reagents used in HIVDR in Africa as it could have negative public relations consequences in their larger markets. This would require further analysis.

But irrespective, the recommendation would be to do FTO to actually inform the direction of research in such consortiums. We would recommend that this would be a condition to receipt of research funding and that funding agencies should assist and provide resources for this process. Information determined by FTO analysis can be used to negotiate with owners of IPR or other rights and perhaps secure voluntary licenses with potential positive public relations for companies concerned. These would need to include isk and liability considerations.

*Licensing terms rather than patents*

It has been argued by a number of groups researching this IP area that it is licensing practices rather than patents *per se*[241] that may impact on access of diagnostics technologies. Our observations tend to support this fact.

Firstly, it would appear that currently patents filed in Africa covering genes, diagnostic methods and reagents are not likely to block access to HIV drug resistance testing in Africa. This is due mainly to the fact that US and European patent holders in this field have not filed for patent protection in Africa but relied rather on their US or European patents. A key problem at present in the HIV drug resistance testing area (and in *in vitro* diagnostics in general), is that most of the critical and key reagents of the methods use commercially available components that are manufactured in US or Europe. Often these patented components are governed by a third-party license which forces the manufacturer to sell products under limited use licenses (e.g., for research use only) irrespective of where the product is sold. So a US or European manufacturer cannot knowingly sell to a customer in Africa that is using the product for another use (e.g., diagnostic use) without the manufacturer breaching existing licensing agreements for components of a reagent that is subject to composition of matter patents in US or Europe. This therefore requires a purchaser in Africa to seek a license for diagnostic use from the patent holder for use in Africa even if the technologies are not patented there. This suggests significant commercial opportunities for African reagent manufactures and also opportunities for sourcing reagent components manufactured in countries where patents are not filed, i.e., other developing countries. Understanding of the ART-A HIV drug resistance testing IP issues has a direct bearing on the WHO HIV drug resistance program. It faces similar issues as the methods use reagent components manufactured in the US that have associated IP rights, and also liability issues cannot be ignored. For instance, if a reagent is used in a diagnostic assay and the assay is demonstrated to be inaccurate then there is a question of who will potentially face liability for any damages arising.

Exclusive licensing practices and the lack of standardised non-exclusive licensing practices have been criticised in the literature. Improvements to the DNA patent and diagnostics licensing system have been recently suggested.[242] Such improvements include:

- Ensuring that there are proper definitions as to what qualifies as research
- Increasing licensing transparency in general, and

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241 Ayme, S., Matthijs, G. and Soini, S. (2008); Van Overwalle, G. ( 2007); Organisation for Economic Co-operation Development (2006). Guidelines for Licensing of Genetic Inventions. (OECD, Paris, 2006).

242 Carbone, J., Gold, E. R., Sampat, B., Chandrasekharan, S., Knowles, L., Angrist, M. and Cook-Deegan, R. (2010), pp. 784-791.

- Providing secure funding of TTOs to allow them to focus on broader social objectives rather than seeing IP rights only as institutional income generators.

However, establishing "norms" in licensing has its own problems linked to what might be regarded as anti-competitive practices, as well as the inability of outside parties to assess transactions without full understanding of all factors driving a licensing arrangement that has been reached by negotiation.[243] The ART-A case supports the use of licensing norms and licensing transparency. More disclosure on licensing practices and licensing costs and how they contribute to final product costs could help in determining IP strategies and identify where research is actually needed. In some cases, where better license terms could be negotiated to improve access, then research to invent around technology would not be required. Increased license transparency could facilitate this, but needs to take into consideration that many licensing transactions are complex and superficial understanding of the arrangements could lead to incomplete conclusions.

*Research use versus commercial use*

The definition of research use versus commercial use currently is not well defined in the diagnostics field especially when it comes to LDTs creating unnecessary uncertainty in this area. Currently most reagent components of ART-A HIV DR testing methods have limited research use only (RUO) licenses but it is not clear what constitutes commercial use. Most laboratories throughout the world do PCR diagnostics for human diagnostics using reagents that clearly state for research use only, not for diagnostic use. This may satisfy certain regulatory requirements in different territories but is not helpful from an IP perspective.

We would argue that transparency by commercial reagent manufacturers on exactly which patents (of theirs and their foreign counterparts) are covered by their products would greatly assist in FTO analysis and inform relevant research. It would also be useful to understand what contribution licensing costs make to the costs of the current commercial assays. It should be borne in mind that licensing costs are not only related to costs of securing patent rights.

A key issue identified here is the terms and conditions of sale and the rights contained therein (as described in Section 5.9.2. and Table 5.2) which is quite separate from IP law and is really part of contract law. Many terms and conditions of sale confer rights of use (e.g., field of use) and these can be modified but need to be negotiated with suppliers. If one wishes to expand the field of use from research to diagnostic use one would need such a license to be included or the terms and conditions of sale to be modified. This would usually be negotiated directly with the supplier. Given the lack of patents filed in Africa, this is most likely to be the area that needs attention in terms of ART-A freedom to operate. An analysis of potential issues surrounding the use of one component, namely the enzyme mixture for nucleic acid amplification, is described in Box III-6 as an example of the issues that would need to be resolved to ensure freedom to operate.

[243] Dilenge, T. (2010), pp. 1242-1243.

**Box III-6: Patent and Licensing Issues with Respect to one of the Reagents Components of ART-A HIV Drug Resistance Test**

*We investigated the use of one of the key reagent components in the ART-A HIV drug resistance test called Superscript ™ III One-Step RT-PCR system with Platinum®Taq High Fidelity, manufactured and sold by Life Technologies in the US and through their South African distributor.*[244]

*Discussion with the Life Technologies licensing office indicated that the product was subject to "numerous" patents from Life Technologies plus multiple third-party patents that the company commercialized under several licenses (i.e., Life Technologies has licenses from third-party patent holders to sell the product with certain field of use limitations). Some were methods patents and others composition of matter patents. Assuming that none of the methods patents were filed in South Africa, they could be considered not relevant to use of the product in South Africa.*[245]

*However, since there were three third-party US composition of matter patents relevant for this product and the product is manufactured by Life Technologies in the US, these needed to be considered. They are:*

1. *Use of detergents with DNA polymerase – US patent # 6,127,155 expiring in 2012 held by Roche Molecular Systems. Diagnostic use requires separate license from Roche.*
2. *Antibody based hot start – US patent #'s 5,338,671 originally held by Kodak but now owned by Johnson & Johnson, and 5,587,287 held by Johnson & Johnson. The patents expire in 2012 and 2014 respectively but would likely need a license from J&J for any use not covered in the package insert.*
3. *Blending of proofreading enzymes - US patent #5,436,149 expiring in 2013 and held by Takara Corporation.*

*Life Technologies has the rights to manufacture, sell, and license the product, which includes these third-party patented technologies for research use but not for diagnostics use. Purchase of the reagent from Life Technologies includes a limited use label license in respect of each of these third-party components.*[246] *Firstly, a limited, non-transferable immunity from suit under patents governing the use of detergents with DNA polymerase (Roche patent) for the purchaser's own internal research. Secondly, a research use only license to the antibody based hot start component under J&J US patents (5338671 and 5587287), and can only be used for research purposes and not re-sold. Thirdly, a limited use label license to the blending of proofreading enzymes under US patent 5436149 (Takara Corporation patent). Any additional use commercial service or diagnostics use requires a license from the patent holder.*

*But interestingly, it appears that Life Technologies is not obliged to police the use of their product but must label it clearly. And as such the product is clearly packaged and marked "For*

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244 Invitrogen[online].<http://products.invitrogen.com/ivgn/product/12574035?ICID=search-product> (Accessed on 1 July 2011).

245 The methods patents were not checked to see if they were patented in South Africa (namely One-step PCR patents held by bioMerieux under US patent 5,654,143 and US patent 5,817,465 and foreign-issued equivalents).

246 For more details on the Limited Use Label Licenses see information accompanying the product insert available at <http://products.invitrogen.com/ivgn/product/12574035?ICID=search-product> (Accessed on 1 July 2011).

*research use only" and the limited use licenses included. It is up to the purchaser to seek a license from the patent holder for diagnostic use. Life Technologies cannot however knowingly sell the product to a customer who they know is using it or re-selling it for diagnostic use (which would be the case for ART-A) as it would breach their current licensing agreements on these composition of matter patents. Life Technologies advised that they had other products of their own not commercially available that were only subject to Life Technologies' intellectual property that could potentially serve ART-A purpose and would likely function as effectively, and could be substituted for the Superscript reagent. This highlights the importance of exploring this option prior to the ART-A consortium R&D started. If ART-A had developed their assay with a substituted enzyme it would have solved a number of these licensing issues.*

*A further consideration irrespective of third party licenses is that if ART-A produces either:*

1. *a "bundled" HIV drug resistance testing product as proposed for re-sale to laboratories, whereby the Life Technologies Superscript product is included in a package of reagents, or*
2. *if individual drug resistance testing laboratories themselves were to purchase the Superscript product and use it for diagnostic use*

*then either ART-A (in case 1) or the laboratory (in case 2) would be in breach of conditions and terms of sale contract with Life Technologies which states it is only for research use (and not for re-sale), and could potentially be sued for breach of this contract. In fact when a quotation for the product is issued by Life Technologies or their authorised distributor in South Africa, terms and conditions are clear that the product is for research use only and not for-resale. In addition, the package insert clearly covers the limited license use and the fact that the product cannot be re-packaged or re-sold.*

*Assuming none of the third-party technologies are patent protected in South Africa (this would need to be determined by checking all the patents "foreign" – i.e., non-US – equivalents to see if any filed in South Africa), ART-A (or an individual laboratory) would have the options to:*

1. *Use the Superscript product and negotiate terms of use with Life Technologies and a commercial diagnostic licenses from the patent owners of the three composition of matter patents, thereby allowing Life Technologies to sell to ART-A for diagnostic use.*
2. *Use another Life Technologies enzyme product (not commercially available) that can perform equivalently but that is not subject to 3rd party licenses and negotiate a diagnostics license and terms of use only with Life Technologies. The field of use could even just be extended to diagnostics use in the quotation provided by Life Technologies.*

*Initial discussion indicated that such a license fee, which would include the right to perform diagnostic test services, is likely to be in the region per lab of: US$50,000 for any diagnostic use; US$35,000 for any infectious disease diagnostic use; and US$25,000 for HIV diagnostic use only. License fees may also depend on test volumes, and Life Technologies did indicate however that all of these license fees would be negotiable. It is possible that they would forgo this fee in the event of laboratories in Africa using the product for HIV drug resistance testing as part of Life Technologies sensitivity to the needs of such testing to be made more affordable in regions where it is critically needed. Life Technologies would in any case benefit from sale of the reagent.*

*Further research desirable*

Finally, it is clear that the decision process over whether and where to file patents by the consortium is difficult and we were not able to make a clear recommendation on this without more research into, in particular, what the licensing options might be for purchase of reagents from US manufacturers for commercial and diagnostic use. However, given the fact that ART-A technologies are in a sense "generic" versions of existing commercial assays (with improved performance, costs and designed for use across a range of instrument platforms), it would seem that in this case patenting of the technologies in Africa or US (or other developed countries) would be unlikely to add significant advantages to the consortium's goal of expanded access, given the other options available. That said, perhaps provisionally patenting one or two of the key inventions would be prudent to buy time to find an interested commercial partner who might want to produce the assay in Africa, if consortium members could afford this. Also, patenting the ART-A technology, which is an improvement of the existing commercial HIVDR technologies, could allow an opportunity for the improvement to be licensed back to one of the existing commercial HIV drug resistance testing manufacturers who may wish to access the improvements without needing to do all the development research. This would be cost effective for them and result in an improved product for end users.

# CHAPTER 6 CONCLUSION

Within the context of international, regional and national IP systems, developmental issues in Africa and available tools for managing IP, we analyzed institutional agreements that cover IP protection and subsequent IP rights that can be obtained and that may impact on the use of ART-A technologies (described in Section 2). We have assessed the implications of the current ART-A consortium agreements with respect to protecting and managing the consortium IP (Section 4). Finally, we have looked specifically at strategic options for ART-A and how IP protection and management options could be used to ensure that the developed technologies are applied in Africa (Section 5) whilst not limiting any potential commercial opportunities for the technology in the developed world.

There is a range of issues that the ART-A initiative will need to consider when taking their technology to market. This includes being mindful of existing sensitivities in the developing world around IP; the need in Africa for access to the technology; and how ART-A's role in improving access to much-needed health technologies is perceived and how a sustainable commercialization model is established.

Irrespective the route followed, they will need to be familiar with the laws (especially new legislation) and regulations for protecting and registering new medical devices both in Uganda and South Africa.

## 6.1 Differing Levels of Development and IP Legislation/Implementation

The levels of development across Africa are different and as a result the ability of different countries to absorb new technologies is very different. Legislation governing IP has been improved significantly as a result of assistance from WIPO and growing capabilities of OAPI and ARIPO. The outcome has been the standardizing, harmonizing and building of IP protection and management tools for Africa. This includes strengthening of, in particular, African information clearinghouses that provide information on patents filed in Africa so that IP can be better managed within the continent. The role of WIPO in continuing to support these structures is important to ensure that IP protection and management structures continue to improve. Despite the good work, there is also criticism of WIPO's technical assistance, which is often said to be too narrow and lacks adequate development orientation.[247, 248]

On the issue of IP and development, whereas some stakeholders encourage substantive and tighter harmonization of national IP systems to meet the needs of IP right-holders operating globally, others believe that national IP systems should be customized to meet local needs and interests, including through the use of TRIPS-compliant flexibilities.[249] In their view, technical assistance should rather focus on fostering the ability of national governments and stakeholders to adjust the IP system to the needs of individual developing countries, with a focus on elements such as institutions for technology transfer, compulsory licensing regimes, and countering anti-competitive behaviour by IP right-holders.[250]

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247 Kostecki, M. (2005).

248 Deere-Birkbeck, C. and Marchant, R. (2010).

249 Ibid.

250 Ibid.

It is clear from this study focused specifically on medical diagnostics, namely HIV drug resistance testing, that the IP landscape is highly technical and complex. Therefore, assistance should focus on enabling developing countries to chart their way through complicated international agreements to reach a more level playing field with developed countries. The instruments exist that can provide the kind of solutions required to address Africa's development challenges, more especially the MDGs. It is the application of those instruments that is severely flawed against the developing world. Stakeholders also argue that the growing emphasis of technical assistance on stronger enforcement may serve perversely to maintain out-dated business models, limit access to knowledge, divert public resources from more urgent tasks, and continue unjustified monopoly behavior on the part of some businesses. Many developing countries, particularly African countries and LDCs, emphasize the need for greater support for local companies, scientists, and artists to make use of the IP system to boost local development and protect their own inventions and creations on the international market.[251] A further implication is that countries need to take more control over what assistance to accept and request.

### 6.2 Access to Knowledge and Encouraging Open Source

Access to knowledge is critical to Africa's development in that it helps promote growth through the spread and distribution of knowledge and knowledge goods and tools around the world. The knowledge that needs to be accessed is in different forms. The first is human knowledge – education, skills, know-how and human capital, and the second is information – including news, medical information, data, and information about government and its processes. A third category concerns knowledge-embedded goods such as drugs and software, whose production requires significant amounts of scientific and technical knowledge. A fourth category involves tools for making knowledge and knowledge-embedded goods, such as scientific and research tools, Internet and communications technology, and computer software. The weak IP systems in African countries prevent the inflow of information drawn from material found in patent claims. This valuable information could improve economic and social development, but also the exchange and sharing of their own knowledge with different global knowledge communities. With the increase in connectivity, including in the developing world, the models of open access to knowledge are having a positive impact on the sharing and exchange of knowledge. Developing countries are being encouraged to adopt open source as a platform for the exchange of knowledge.[252] This is demonstrated by the Salvador Declaration on Open Access, which urges "governments to make Open Access a high priority in science policies." This includes requiring that publicly funded research is made available through open access and considering the cost of publication as part of the costs of research.[253]

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251 Ibid.

252 Okediji, R. L. (2004).

253 Biomedical Central [Online] <http://www.biomedcentral.com/developingcountries/resources/> (Accessed 21 February 2011).

### 6.3 Obstacles to Access to ART-A Technologies

In the case of ART-A, the current obstacles to access to technology in Africa appear to be unrelated to patents filed in Africa. Our analysis shows that most patents, covering the diagnostic methods or reagents required for ART-A, are not filed in Africa. ART-A has developed technology that currently utilizes reagents or components that are manufactured outside Africa, in territories where these reagents and components are patented. The sale of these products to African customers is more likely therefore to be controlled by terms and conditions of sale or contractual law, not IP law. As a result it is more likely that restrictions imposed by these rights or excessive terms will have a larger impact on ART-A technology access than any patent or IP laws.

Where there are patents filed in Africa on key technologies that are required for HIV drug resistance testing (e.g., PCR), these patent filings are limited largely to South Africa and are expired or about to expire. In any case, there has not been strict enforcement of such patent rights by developed country patent owners in Africa. Many private and state pathology laboratories in Africa who have purchased such reagents from local subsidiaries or agents of developed country manufacturers utilize them freely without concern of patent infringement. Perhaps this is due to public sensitivity about developed country companies profiting from disease in Africa. However, it creates a degree of uncertainty as to whether infringement action suits are likely. That said, a clear opportunity exists for African commercial enterprises to manufacture such reagents and sell them freely in Africa. Why this has not happened to date is unclear.

### 6.4 Barriers to African Manufacture of Diagnostic Products

It may be that African markets in themselves are not yet large enough to support the required investment in high technology manufacturing infrastructure. Because these products are patented in developed countries, a manufacturer in Africa could not sell them in those countries without a license potentially making them uncompetitive. As a result, it may be that reagents cannot be produced in Africa at sufficient economies of scale where they can compete on cost even with imported licensed products. In the case of the HIV monitoring test market the numbers of patients on ARV therapy, could eventually reach a critical size where such manufacturing becomes viable.

It may also be that the technology components of the manufacturing infrastructure are covered by patents, although whether they are covered or not in Africa needs to be determined.

In an ironic twist, therefore, the future obstacles to the longer term availability of ART-A technologies may be due to the fact that their component technologies are not patent protected in Africa. Essentially no monopoly position can be acquired by an African manufacturer through patent rights to provide an opportunity to build African manufacturing capacity. The absence of the ability by developed country diagnostics companies to provide an exclusive license to manufacturers located in Africa limits the ability of a local manufacture to compete with those from abroad. This would suggest that a lack of patenting in Africa, especially where those patents are filed in developed countries, is actually what is responsible for lack of commercial manufacturing activity. This is speculative, but in a sense it argues that a potential obstacle to knowledge and technology absorption is in fact the lack of protection

and subsequent exploitation of IP rights in African or developing territories. Without commercial players being incentivised or provided some exclusivity to manufacture medical diagnostic technologies, a medical diagnostics manufacturing industry cannot be created in Africa and Africans will remain net importers of finished diagnostic products.

More research is definitely needed to understand why medical diagnostic and research reagent manufacturers are not situated or starting up operations in Africa despite the large and growing market.

### 6.5 Other Key Challenges

Despite these complex issues around IP rights, contract law and manufacturing incentives, there are other critical issues that could prevent uptake of ART-A technology, like the infrastructure of laboratories, human resource expertise, reliable reagent supply chains and adequate equipment maintenance support, coupled with insufficient ability of either governments or patients to pay for testing.

Both South Africa and Uganda have similar challenges together with specific ones unique to each country. A challenge common to both countries, but to differing degrees, is low R&D output relative to more developed countries.

#### 6.5.1 Uganda's Challenges

R&D institutions in Uganda lack the resources, capacity and capability to carry out advanced research that can generate high volumes of R&D outputs, including patents, publications and human resource expertise. This in turn limits the ability to absorb new technologies. Even in HIV/AIDS research, an area where Uganda has great opportunity to lead, the general R&D output is low. The problems faced include:

- **Low domestic patenting rate.** One of the benefits of the patent system is that the publicly available patent claims facilitate knowledge dissemination. In a case where there is low internal patenting, local scientists miss out on country-specific knowledge. As a result, much-needed data that can assist the development of developing countries is not shared and disseminated.
- **High reliance on donor funding**. Because institutions are poorly resourced by their own governments, they are compelled to follow the money provided by donors. While donor funding has immense benefits, often it comes with funding conditions and requirements which set and influence the research agenda. As result, certain research of strategic importance is neglected. An example would be an investment into basic research to understand the virology, microbiology and cellular and genetic composition of the HIV virus.
- **New legislation and policy** – training is required to bring the R&D community up to speed with new legislation, processes and procedures. It is only when the new laws are understood that the research community is able to apply them to their benefit, such as in the protection of new IP, the licensing in and licensing out of research technologies.
- **Limited IP resources and capacity** – the Uganda National Council for Science and Technology has been given the mandate to protect IP emanating from local research activity and to establish a National IP Office. The council lacks the financial and human

resource capacity and IP expertise to set up the systems needed to protect IP derived from R&D and to establish the national IP office.

### 6.5.2 South Africa's Challenges

Despite the comparatively high R&D investment and research capacity in South Africa as compared to Uganda, South Africa's patenting and publication rates are declining.[254] This is concerning for a country that has undertaken to move towards a knowledge-based economy and is well-placed to lead the development and manufacture of HIV/AIDS medicines and related health technologies. However, it has been suggested that South Africa's research effort in HIV and AIDS despite being large relative to its size is too fragmented and should be concentrated in a few key institutions.[255]
The challenges faced are:

- **High number of foreign patents** – Relative to other African countries, South Africa is the one country on the continent where foreign patent owners tend to acquire patents. As a result, South Africa needs to obtain licenses to access the IP required to commercialize or manufacture certain medical technologies.
- **Implications of the IPR Act for Publicly Funded Institutions** – as discussed earlier, the IPR Act has the potential to stave off private sector participation in research. The likely consequence of this is a decrease in private sector partnering with local R&D institutions, less contract research undertakings and fewer knowledge and technology transfer opportunities. Evidence of this, however, remains to be demonstrated.
- **High incidence of HIV/AIDS and unwieldy regulatory environment** – despite the advanced health and research infrastructure that exists in South Africa, the country has lagged behind others on the continent in introducing high impact interventions to control the spread of HIV/AIDS. Furthermore, the country's regulatory processes for introducing new medical products and conducting clinical research in HIV/AIDS are plagued by bureaucratic formalities that slow down the introduction of new health technologies.

## 6.6 The Opportunities for ART-A

Despite these challenges, the ART-A consortium does have the ability to use standard IP protection and management models that are used throughout the world. Encouragingly, our analysis here showed that ART-A effectively established a protective commons through its agreements between the parties, even though a formal protective commons platform like Cambia's BiOS was not used. International, regional and local institutional policies do apply to and support these approaches. A potential issue in this regard relates to the South African Intellectual Property Rights from Publicly Funded Research and Development Act[256] which affects the determination of ownership of ART-A technologies where South African

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254 WIPO (2009).

255 Pouris, A. & Pouris, A. (2011), pp. 541-552.

256 South Africa 2008. *Intellectual property rights from publicly financed research and development act, no. 51of 2008.* Pretoria: Government Gazette. < http://www.dst.gov.za/publications-policies/legislation/IPR%20Act%200f%202008.pdf> (Accessed on 1 July 2011).

institutions may have rights in IP ownership. This would need to be investigated further should ART-A decide to file for patent protection on any aspects of the technology.

Thus if ART-A can identify commercial partners who can manufacture components or "bundled" kits based on their technology, they should pursue formal IP protection (e.g., trademarks or patents) and management (e.g., licensing) strategies. The key issue is whether they can identify the interested commercial partner. If not, then the approach of publication and open source dissemination should be considered. This relies on African laboratories to implement the technologies on a dispersed and fragmented scale and therefore is unlikely to achieve the critical mass to drive down costs assisting in further technology uptake. The problem with finding a commercial partner in a consortium of this nature is who will actually be incentivised to assume that primary role, as it requires expertise and resources, and is generally beyond the scope of a largely academic consortium. This is not attractive if that party is not the IP owner. Sufficient incentives to commercialize do not really exist to overcome the large investment focus and effort required.

To improve the relationship between IP and research and development we identified probably the most important issue to be an in-depth understanding of freedom to operate. It is recommended that FTO analysis be conducted at the start of such funded research projects or even perhaps prior to funding. This would not only identify upfront the potential IP constraints, but also would really help to inform the actual research that needs to be done, given not just the technology constraints but also the IP constraints resulting in more relevant research activity. A comprehensive FTO analysis requires expertise and resources. Again, this is an area where TTOs can assist and lends support to the call for their further strengthening. In fact, the role of TTOs is critical in assisting transfer of information to commercial partners within developing countries. Particular focus should be given to how to assist and develop TTO capacity to accomplish this. In conducting this research we realized the breadth and complexity of the subject matter, especially when one considers issues from a patent on a single component of a technology right up through institutional policies and national and international laws. All work that seeks to educate developing and developed world practitioners in this area should be encouraged.

That said, there is an immense opportunity for ART-A to make a significant impact both in Uganda and South Africa by providing an affordable and accessible diagnostic tool for detecting drug resistant HIV. Not only can ART-A contribute by introducing a new testing methodology, but through the application of this technology it is possible to set up systems to monitor, record and report the prevalence of HIV resistance.

### 6.7 Opportunities for Improving African R&D Output

A key question is how to encourage and support African companies and institutions in developing solutions which translate into products or services and thereby revenues. The aim is to create wealth for these countries which in turn allows for adoption of more technologies that benefit the health of their populations. Some of the challenges identified present opportunities for both countries that should be further explored. In the case of Uganda these include:

1. **Low rate of foreign patenting** – with the low number of foreign entities patenting in Uganda, this gives Uganda the opportunity to access patented medical technologies and research technologies and tools to benefit its own R&D activity and any pharmaceutical manufacturing potential that exists.

2. **Promote local incremental innovation** – Uganda's efforts to partner with Indian generic companies to build local production capacity, especially for ARVs, provide a number of public health and economic development benefits.[257] Suggestions have been made that the government should evaluate proposals to provide local pharmaceutical producers with temporary protection from overwhelming foreign competition. Such suggestions need to be carefully considered for Uganda to build a viable pharmaceutical manufacturing capability.

3. **Government-led effort to address the HIV/AIDS epidemic** – there is widespread recognition of Uganda's concerted effort to control and monitor the HIV/AIDS epidemic. As a result, Uganda has benefited from donor funding, knowledge transfer of expertise and infrastructure support provided by the international development community, specifically to bring HIV and AIDS under control.

4. **Pockets of R&D strength** – One of the research areas in which Uganda has developed substantial capacity is in pre-clinical and clinical trial development for HIV/AIDS drug development. The data generated during such trials is in itself valuable intellectual property. Such intellectual property could be used to benefit and advance further HIV/AIDS research on the continent.

In the case of South Africa this includes:

1. **Relatively advanced IP system** – South Africa has gained experience in managing intellectual property derived from R&D activity. Key R&D institutions have newly established technology transfer offices and generally, the research community is cognizant of the importance of IP. As a result, South African institutions are able to establish sophisticated IP management strategies designed to overcome barriers to access to medical technologies and facilitate the exchange of knowledge and technologies between local and international researchers.

2. **Relatively good R&D infrastructure and resources** – Relative to other African countries, South Africa has a better-resourced and -funded R&D sector. The consequence is that South Africa is often the partner of choice in international collaborations. Such collaborations assist in building local R&D capacity and provide training opportunities.

3. **Manufacturing capacity and capability –** Several of the leading international pharmaceutical companies have a presence in South Africa, largely in areas of clinical

[257] United Nations (2010).

trials, packaging and some formulation and manufacturing, but no R&D. In addition, South Africa has some of its own manufacturing capability. Incentives can be provided to encourage private industry to invest in the establishment of new manufacturing enterprises for the production of medical diagnostic products.

### 6.8 Broader Suggestions and Recommendations

Taking a broader view than just ART-A and HIV diagnostics, we propose the following recommendations for South Africa, Uganda, and African countries in general:

1. **Prioritize and Establish Research Agenda**
   Such an agenda should identify priority research areas, locate funding sources and determine expected research output. This should coordinate research activities so as to optimize the available research capacity and avoid ineffective duplication of effort. The strategy should be shared with the donor community for them to understand the country's strategic research priorities and they should be given an opportunity to contribute to the implementation of the strategy.

2. **Build IP Management Capacity**
   There is a need to identify critical IP training needs and select dynamic individuals for training on IP in the medical R&D field. Here we have in particular identified the ability to perform FTO analysis prior to technological research as one such need. Training in this area is required and should include introduction of IP management strategies, policies and processes and procedures at the institutional level, and ways for imparting knowledge and expertise to fellow colleagues and decision-makers in government and R&D institutions.

3. **Identify funding and resources required to drive R&D in priority areas**
   There may be areas of research not readily funded by donors that are important in tackling the HIV/AIDS epidemic through R&D. Identifying such areas and determining how such research can be supported and strengthened. HIV drug resistance testing is one such opportunity.

4. **Work closely with donor funders**
   Developing countries need to find a mechanism to work in a cooperative manner with donor funders and to be more proactive. This way, funding can be channelled towards areas of greatest need and used to provide sustainable long term solutions, while at the same time, ensuring that funders deliver on their objectives. ART-A is a good example of this as HIV drug resistance testing is needed, but currently there is little commercial activity in this area addressing the need for reducing costs.

5. **Monitor and Evaluate R&D Outputs**
   This ensures that it remains relevant to the health needs of the country and allows tracking of a country's and funders' return on investment. It allows for identifying more efficient and productive areas and national strengths. In addition, the introduction of incentive models that will encourage local R&D institutions to increase their R&D output

is needed. This is especially true in areas where new medical technologies are required to address the challenges of HIV/AIDS.

As a final suggestion to provoke discussion in this area, we would suggest that both developing and developed country innovators should be filing patent protection in African countries for products or inventions that have significant markets (e.g., HIV diagnostics). This could then enable, through progressive licensing practices, commercial enterprises in Africa to exploit these technologies and share in the rewards. If those enterprises cannot be given the necessary protection and incentives to do this in Africa, such enterprises will not come into being, and therefore Africa will not be able to create wealth necessary to sustainably address the Millennium Development Goals.

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# PART IV

## SYNTHESIS, CONCLUDING REMARKS AND RECOMMENDATIONS

**By:**

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**and**
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**(in cooperation with the postdocs,**
**as well as the Steering Committee members)**

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**SYNTHESIS**

# Synthesis

## 1.1 Introduction

Intellectual property rights (IPRs) play a central role in the management and sharing of knowledge and technology in innovation systems. On the one hand, IPRs are meant to protect knowledge, to stimulate investments in innovation and to support R&D following inventions. As such, IPRs might regulate technology transfer with advantages for all partners sharing their knowledge. On the other hand, IPRs might as well reduce use of technologies that have been developed on the basis of IPR protected knowledge, because commercialization of knowledge impedes innovation towards technologies for societies that cannot provide a legal framework to effectively manage IPRs or that cannot promise financial returns.

The pilot-project that was the subject of this study aimed to research the role of intellectual property rights in the management and sharing of knowledge and technology for development, in particular, the realization in Sub-Saharan Africa of the Millennium Development Goals, notably MDG 1 ("Eradicate extreme hunger and poverty"; target 1c: "Reduce by half the proportion of people who suffer from hunger") and MDG 6 ("Combat HIV/AIDS, Malaria and other diseases").

This central question was divided in four sub-questions: 1) what are the obstacles created by IPRs for the realization of development objectives? 2) What are the 'best practices' and positive experiences with IP solutions in the context of development in the Sub-Saharan African region? 3) How can the relationship between IP and development (the achievement of the MDGs) be improved? 4) What practical recommendations can be formulated with regard to the valorization of the present research project?

The answers to these questions have been formulated by three teams of researchers in three sub-projects, each covering a different area and applying a different approach (see below). Sub-project I (see Part I), *Trade vs. Development: the International Intellectual Property Rights' Regime and the UN Millennium Development Goals*, outlines the development and history of IPR law in general and frames the obstacles to development created by IPR law and the application of the international IPR regime to developing countries in Sub-Saharan Africa. Sub-project 2 (see Part II), *Agricultural Seeds That Reduce Hunger and Poverty – Policies, Perceptions and Practices in Intellectual Property Rights* examined the relationship between IPRs, agriculture, and MDG 1c. For that purpose, a team composed of researchers from the Netherlands and Uganda analysed the roles that different IP policies and practices play in agricultural research and development trajectories in both a developed and a developing context. Sub-project 3 (see Part III), *Affordable HIV Drug Resistance Test for Africa (ART-A) Intellectual Property*, focused on the relationship between IPRs, the medical sector, and MDG 6. It examined a rather unique European and African research consortium called the Affordable Resistance Test for Africa (ART-A) that was established to develop technologies for affordable HIV drug resistance testing in Africa.[1] This consortium is a public-private partnership (PPP) and presented a great opportunity to study international, regional and institutional intellectual property laws and policies and how they affect access to knowledge in Africa. The researchers investigated the intellectual property landscape of this consortium

[1] <http://www.arta-africa.org/>

in an attempt to identify how data and research output can be shared and protected by the consortium, and how knowledge assets developed by the consortium can (and should) be managed.

The conclusions and recommendations of the individual sub-projects can be found at the end of each sub-project (see Part I, II, and III).

The purpose of the synthesis is to summarize and compare the findings of the three sub-projects, in order to formulate an answer to the central question. As to the comparison of the findings, it might be good to recall the methodology of the report. As explained in the Introduction to this report, the combined "North"- "South" research teams and the inter- and trans- disciplinary approach in this research project provided the following dimensions to the research:

- Three different countries have been given special attention: Uganda, South Africa and the Netherlands.
- Further to that, four geographical levels have been researched: a) the *local level*: farmers in Uganda, b) the *national level*: governments in the Netherlands, Uganda, and South Africa c) the *regional level*: the OAPI, ARIPO, and the EU (to some extent); and d) the *global level*: the WTO, UPOV and WIPO.
- As regards the different actors, three levels have been discerned: a) *the stakeholder level*: local farmers and breeders in Uganda, researchers and staff at laboratories and, to some extent, healthcare consumers in Sub-Saharan Africa. b) *The institutional level*: research institutes and universities in the Netherlands, Uganda and South Africa. c) *the governmental level* in the Netherlands, Uganda and South Africa.
- In addition, two different sectors have been researched: the medical sector and the agricultural sector.
- Finally, the relationship between IPRs and MDGs has been assessed by three different approaches: a) *an overall approach*, providing insights in historical developments and present international debates on the relation between IPRs and MDGs (sub-project 1), b) *a chain-analysis* conducted on IPRs in the agricultural context (sub-project 2) and c) *a micro-analysis* of a concrete model in the medical context (sub-project 3).

These different dimensions, and the structure they provide, will reappear at several places in Part IV, there where they add new insights or conclusions. In general, Part IV will be structured along the four sub-questions mentioned above. The synthesis and concluding remarks will concentrate on the first three sub-questions. The practical recommendations – based on the answers to sub-questions 3 and 4 – will follow in the last section of Part IV. It goes without saying that further substantiation and argumentation can be found in the sub-reports themselves.

### 1. 2 The Double Role of IPRs in the Context of Facilitating the MDGs Nos. 1 and 6

Central to the findings is the observation, found in each part of the research, that IPRs play a *double role* in the (non-)realization of the Millennium Development Goals numbers 1 and 6.

*On the one hand*, they play a negative role where they create obstacles for the development, transfer and accessibility of knowledge and technologies for the benefit of Sub-Saharan African countries. These obstacles can be divided into five aspects:

- Imbalances in the international and national IP systems.
- The existence, in developing as well as developed countries, of perceptions and high expectations regarding the revenues of IPRs.
- The complexity of the IP landscape. Both in the agricultural and medical sector it is difficult and expensive to identify and secure the freedom to operate for proprietary technologies for humanitarian use.
- Limited development considerations at companies.
- Specific aspects of IPRs having the potential to hamper pro-poor innovation, such as the high costs of patenting, and the distorting and consolidating effect of patents.

Each of these aspects will be discussed in further detail in the Sections 2.1 to 2.5. It is important in the context of describing the negative role of IPRs in relation to development goals to also refer to the existence and application of several pro-development instruments, options, and flexibilities within national and international IPR systems and to analyze why these pro-development instruments, options and flexibilities are hardly being used by stakeholders (see Sections 3.1 to 3.4).

*On the other hand*, apart from the drawbacks of the IPR system and of the way IPRs are used (and not used) in the context of the realization of development objectives, there also remains a clear need for a well-functioning and improved IP system. This possible positive role of IPRs for the achievement of development objectives will be discussed in Section 4.1, together with the core obstacle to actually playing this role: the lack of an adequate legal and administrative infrastructure (Section 4.2).

Subsequently, Sections 5.1 to 5.3 examine how the relationship between IPRs and the achievement of development objectives as formulated in MDGs 1 and 6 can be improved, by mitigating the negative role played by IPRs in the achievement of the MDGs, and by better harnessing IPRs for development objectives.

## 2. IPR-related Obstacles for the Development, Transfer and Accessibility of Knowledge and Technologies for the Benefit of Sub-Saharan Africa.

### 2.1 Emergence and Consequences of an Un-balanced International IP System

The fact that the international IP system (in particular TRIPS) has in essence not been designed to take care of the specific needs of developing countries has a widespread impact on the relation between IPRs and the achievement of the MDGs. Most obstacles to sharing knowledge for development purposes identified in this research can be traced back to the existence of imbalances in the international IP- system. The research shows, *inter alia*, the following elements:

- The rationale underlying IP protection is that it is not an end in itself, but a rather a legal instrument to balance private and public interests in research and innovation.
- The basic principles of the international IP system date back to the 1883 Paris Convention. Today, the landscape of "private and public interest" is entirely different from that of 1883. Consequently, there is an evident need for adjustment.

- A recurring theme in all three sub-projects is that the international IP-system is an unbalanced system, unable to promote in an adequate way the needs of developing countries.
- The underlying cause is that the TRIPS implementation process in Sub-Saharan Africa has been motivated by the protection of the IP originating from developed countries rather than as an instrument for broad-based innovation, competition, and economic development.
- It remains a question whether IPRs, which may be seen as market instruments, could be expected to contribute to non-market actors, such as the poor farmers and healthcare consumers targeted by the MDGs.
- Developing countries, in order to be TRIPS compliant, and sometimes even TRIPS-plus compliant, have been pushed to modify – in some cases significantly – their legislation, legal systems and IPR administration far beyond their local needs and objectives.
- The direct consequences of this top-down push for IP policymaking are visible in, *inter alia*, Uganda, where little room was left for the development of robust policies directly linked to national and local needs and objectives. The international IP system has developed without specific reference to the needs of Ugandan innovators and technology users and lacks a focus on resource-poor farmers and food security.
- The formulation of IP policy at the national level in most African countries is driven by the international agenda based on the WTO TRIPS Agreement, bilateral and regional trade agreements, and the policies of international agricultural research and funding agencies. This makes it nearly impossible for developing countries themselves to balance the rights of inventors in the developed world with those of their societies at large. Capacity development programs (e.g., by WIPO and bilateral donors) furthermore strengthen the vision in local institutions that the rules that operate in OECD countries are leading and optimal.

The following observations from the reports illustrate the widespread impact of an unbalanced international IP system:

- Pro-development options in existing IP instruments are hardly known or understood, let alone used.
- South Africa and Rwanda have attempted to use compulsory licensing and other flexibilities in order to access essential medicines, but in practice this is not easily achieved. The exact reasons for this practice remain unclear.
- Companies tend to apply very restrictive conditions in licensing contracts and MTAs, restricting any use for local development.
- There is a lack of development considerations in the IP policies of almost all actors, including, for instance, the Netherlands in relation to the Dutch agricultural research system.
- Even where references to the '*common good*' – see the Introduction of the report – are visible in academic debates and advisory reports, they are absent in daily IPR policies and practices.
- The valorization of research is in most cases narrowly understood as the need to turn knowledge into (economic) value for Western societies, the Netherlands not being an exception.

### 2.2 Perceptions Regarding Financial Implications of IPRs

(Unjustified) perceptions and expectations regarding the revenues of IPRs have a negative impact on pro-development decision-making. The reports provide the following illustrations:

- *On the one hand,* there are several perceptions and expectations, particularly in the "South", as regards the financial benefits IPRs can offer. For instance, the analysis conducted with agricultural research managers throughout Africa showed that they hope that:
  - Revenues accruing from the licensing of IP could help boost the productivity and innovation capacity of individual scientists, as they will be rewarded for their innovation work.
  - IP could become a potential additional source of revenue for their institutes.
  - IP could provide a basis or mechanism for building public-private partnerships that could help move new technologies into the market and hence make them accessible by farmers.
- While it is clear that the majority of the rural populations in Uganda and elsewhere in Africa depend on a wide range of crops to mitigate the risks of hunger, there are signs that the IP policy landscape in Africa's agricultural research institutions and universities is changing towards more commercially viable crops and commercially viable farmers, and is moving away from poverty reduction goals.
- *On the other hand,* there are perceptions and hesitations, in particular in the "North", regarding the financial consequences of the application of humanitarian use licenses. Such licenses provide the possibility for inventors and technology suppliers to share their IP for humanitarian use while maintaining the incentive function of exclusive rights for commercialization.
- For instance, it appeared that in the Netherlands there is very little knowledge of humanitarian licensing strategies and the idea that humanitarian licenses can negatively affect one's own public and private interests is widespread. Therefore, Dutch public research organizations make very little use of humanitarian licensing strategies.
- It was reported several times that many companies in the "North" have reservations with respect to the application of such licenses because of the risk that a protected technology, which is provided royalty free for humanitarian use, ends up in a competitive product on the world market.
- Consequently – and apart from non-economic arguments related to the '*common good*' debate – public research organizations are reluctant to make humanitarian licensing a standard policy because they fear that this will lead to fewer contracts and partnerships with companies.

### 2.3 The Complexity of the IP Landscape: Understanding and Securing the Freedom to Operate for Humanitarian Use

The sub-reports 2 (on agriculture) and 3 (on pharmaceuticals) make clear that both with regard to the development of agricultural and medical biotechnology it is essential but difficult, expensive and time-consuming, to understand and secure the freedom to operate for humanitarian use. They provide the following illustrations of such (terminological) difficulties:

- IP *protection* refers to the act of securing one's intellectual property to prevent unauthorised use of the IP by a third party.
- IP *exploitation*, on the other hand, takes place when one exercises one's rights to exploit certain IP. IP exploitation encompasses a wide range of activities which include technology transfer, research collaborations where protected inventions are incorporated into new products, processes and services, sale of IP titles and licensing and commercialization.
- To be able to exploit IP one needs freedom to operate (FTO), meaning that the new IP being developed will not infringe valid intellectual property rights of others. If it does then IP rights need to be obtained to ensure FTO, and these may often not be obtainable. Thus, a good understanding of the FTO is essential for technology development and transfer.
- The purpose of an FTO search is to find relevant unexpired patents or patent applications that could become barriers to develop or to commercialize one's own IP in the countries targeted for the production, use and sale of the proposed technology product. An FTO analysis can also assess the limitations of existing patents that provide opportunity for newly created IP. Finally, an FTO analysis can also help to identify the need to invent around blocking patents and alert consortia to cross-licensing or collaboration opportunites.
- Public-private partnerships (PPPs) that seek research funding for technology development often focus on the technology and overlook the need for, or do not have resources to do, a proper FTO analysis that can inform as to the research path to be taken. Adequate funds are often lacking.
- The sub-reports emphasise that FTO analyses should ideally be done prior to, or at very least, in parallel with technology development. Moreover, they underline that the role of technology transfer offices (TTOs) in assisting research consortia to do an FTO analysis cannot be overemphasised, while African countries clearly need support in developing that capacity.
- Sub-report 2 observes that securing the FTO causes problems in relation to the humanitarian use of IP rights (licensing, patents) in agricultural biotechnology, in particular where local public or private partners are restricted in the further development and use of the patented technologies for pro-poor objectives. From the sub-reports it is evident that local TTOs often lack the negotiation skills needed to counter the positions taken by the patent holders.
- Moreover, FTO causes inertia in the pursuance of humanitarian uses, in the sense that the costs of carrying out an FTO search exceed the economic benefit (in fact there is none in humanitarian use) in the resulting license. The costs are simply unrecoverable.
- However, it should also be realized that the utility of patent searches might be small, as many products and inventions are not patented in smaller economies such as those of most Sub-Saharan African states. But despite that, institutes tend to be afraid of making mistakes and refrain from using technologies that may be patented elsewhere.

### 2.4 Limited Development Considerations at Companies

Through (a) restrictive licensing practices, (b) restrictive use of material transfer agreements (MTAs) and (c) the use of blocking patents, companies and research institutes can severely

hamper research for development. It is particularly in such practices of (some) companies in the "North" that the tension between trade interests and development goals becomes apparent. The sub-reports again provide a range of illustrations:

- (a) It appears that in the agricultural sector the *restrictive* licensing conditions of some companies in the "North", and the weak research exemptions in most national IP laws, in practice do block the availability of protected technologies for scientific research, and for sure for development and use.
- In the medical sector also, reference is made to the problem of *exclusive* licensing practices and the lack of standardized non-exclusive licensing practices.
- (b) The restrictive use of MTAs by companies creates serious obstacles for pro-poor innovation projects.
- MTAs can facilitate the exchange and scientific use of (IP protected) research materials but normally do not allow for product development or any commercial applications of the material. This creates serious obstacles for pro-poor innovation projects, as these often involve applied researcher trajectories that, for example in the agricultural context, aim at the local development of improved seeds for smallholder farmers.
- In the agricultural sector, some companies are reported to include such restrictive conditions in their MTAs that the scientists preferred not to do research on or with these technologies.
- Also in the medical sector, instances of restrictive or unreasonable conditions in MTAs are reported.
- (c) Companies use the practice of blocking patents, thus primarily serving strategic objectives – for instance, to block competitors in the market or in a research area – rather than commercializing the very invention that is protected. Such practices can severely hamper the use of innovative technology for development purposes.

### 2.5 Specific Aspects of IPRs and Especially Patents have the Potential to Hamper Pro-poor Innovation

IPRs, and especially patents, have the potential to hamper pro-poor innovation in or for developing countries. Specifically in relation to patents, several aspects hampering the access to knowledge in the context of pro-development innovation were observed.

- Patent maintenance, transaction and litigation involve high expertise and costs. Dutch universities and even multinational companies report having difficulties with bearing these costs. This leaves many questions for the position of research organizations in developing countries or pro-poor research initiatives. Here the lack of resources makes it difficult to use the patent system (apply, defend, get access to, etc.)
- If patenting costs are high then it may mean that inventors do not file patents and hence cannot protect their inventions. As a result, there is no commercial incentive for development of related products and services and hence no real innovation. An invention that is never used cannot really be regarded as an innovation.
- Patenting costs have to be deducted from research investment at the research institute level. Life science multinationals spend much more on legal counsel than on research. It could be questioned whether this is optimal from society's point of view.

- IP transaction costs can form a serious impediment to humanitarian research projects as the return on investment for such projects is likely to be very small.
- Patent enforcement is costly, not only because of litigation, but also from the prespective of a potential wasted technology development investment. Therefore ideally, as also stated above, an FTO search should be conducted even before undertaking new research.
- Patent databases form a valuable source of information. However, due to a lack of technical know-how in developing countries the information disclosed is not always sufficient for researching the described inventions even where the patent is not registered in the developing country.
- Some IPR systems make reuse of seed illegal (patent), others do not allow the exchange and sale of farm-saved seed (breeder's rights according to UPOV).
- The current patent system contributes to further consolidation in the seed sector.
- The use of 'blocking patents' (see par. 2.4) is relevant here as well.

The studies also underline that the negative effect of IPRs in Sub-Saharan Africa should not be overstated, as there is no local use of IRPs.

- Both studies reveal that patents are hardly registered in Sub-Saharan Africa. Where there are patents filed in Africa on key technologies that are required for HIV drug resistance testing, these patent filings are limited largely to South Africa and a few other countries and are expired or about to expire. In any case, few drug-related patents have been subject to private litigation in Sub-Saharan Africa.
- (a) The agricultural project points out that most protected technologies today go beyond the absorptive capacity of developing countries and that there is much non-patented technology and knowledge available that is more relevant for these countries at this moment. However, the study also underlines that several protected biotechnologies, e.g., insect resistance and drought tolerance, are increasingly relevant for developing countries, and that both technologies and plant materials are increasingly protected.
- Furthermore, it is pointed out that the lack of effective IPRs could also hamper some basic investments in local breeding programs and uptake of varieties in commercial seed chains (see also Section 4)
- (b) From the medical project (sub-project 3), it appears that it is exploitation and licensing practices rather than patents *per se* that may impact access to diagnostics technologies.
- In case of ART-A technologies, most of the critical and key reagents use commercially available and patented components that are manufactured in the US or Europe. Often these patented components are governed by a third-party license which forces the manufacturer to sell products under limited use licenses (e.g., for research use only) irrespective of where the product is sold. So a US or European manufacturer cannot knowingly sell to a customer in Africa that is using the product for another use (e.g., diagnostic use) without the manufacturer breaching existing licensing agreements for components of a reagent that is subject to composition of matter patents in the US or Europe. This therefore requires a purchaser in Africa to seek a license for diagnostic use from the patent holder for use in Africa even if the technologies are not patented there – so contract law *may be* at least as relevant in such cases.

- This suggests significant commercial opportunities for domestic reagent manufactures and also opportunities for sourcing reagent components manufactured in countries where patents are not filed.
- Relative to other African countries, South Africa is the one country on the continent where foreign patent owners tend to obtain patents. As a result, South African institutions need to obtain licenses to access the IP required to commercialize or manufacture certain medical technologies.

## 3. Challenges to Using Pro-development Options in Existing National and International IPR Legislation

In the light of the abovementioned IPR-related obstacles to the achievement of development objectives, it is important to realize that national IP legislation and international IP treaties contain several clauses and flexibilities aiming to facilitate developing countries and to enhance research and innovation for development objectives. The studies describe several instruments in national IP laws and international treaties that can secure and facilitate the accessibility or transfer of IP-protected knowledge, materials and technologies for development purposes. It appears, however, that such instruments – such as compulsory licenses, research exemptions, disclosure conditions in patent law, exhaustion of patent rights, exception to patent rights, prohibition of anti-competitive practices, government use, and provisions specifically for the agricultural sector such as the farmers' privilege and the breeder's exemption – are hardly known, understood, or used by stakeholders. This problem exists along the whole pro-poor research chain, in the "North" as well as the "South", with regard to all stakeholders (ministries, research institutions and universities, companies) and both in the agricultural and the medical field.

The following factors appear to contribute to the failure to use the existing pro-development options:

### 3.1 Inadequate Legislation

- National IP legislation can be a determining factor in encouraging the transfer of knowledge and technology for development objectives. Dutch IP law, for instance, lacks a specific development clause and only includes impractical conditions on compulsory licenses. Despite several international agreements that emphasize the responsibility of the industrialized counties to promote technology transfer to least-developed nations, including TRIPS Article 66.2, no such reference can be found in Dutch IP law.
- The conditions included in Article 57 of the Dutch Patent Act on compulsory licensing make effective use of this instrument very difficult, which led to very few applications and no grants in the period 1995-2005.
- In Uganda, by removing aspects of the Farmers' Rights from the draft of a new bill on plant variety protection, the opportunity was missed to effectively balance the rights of breeders and farmers and to acknowledge the central role and importance of the informal seed system.

- As an example of 'over'-legislation could serve the 2008 South African Intellectual Property Rights from Publicly Funded Research and Development Act which might deter private sector participation in research (see below).

### 3.2 Lacking Development Considerations in IP Policies in the Netherlands as well as in Uganda

Both in the Netherlands and Uganda development considerations are lacking in the IP policies of almost all actors in the public agricultural research system. In the Netherlands, this is due to a widespread lack of relevant knowledge. In Uganda, it is mainly due to the absence of effective institutional coordination and a focus on the potential revenues of IP for institutions and scientists. South Africa seems to be one of few positive exceptions to the rule that development considerations are absent in the national IP policy. The reports provide the following illustrations and evidence for each of the countries:

As to the Netherlands:

- The IP policies of Dutch ministries, funding agencies, national research programs, and public research organizations lack specific references to international development. Valorization of research, narrowly understood as the need to turn knowledge into (economic) value for the Dutch society, is the primary driver for IP policymaking in the public research sector.
- This situation seems due to the following reasons:
  - There is no general IP policy at the ministries that finance agricultural research and international development research, while opinions diverge on the need for such a policy.
  - Awareness among policymakers is low with respect to consequences for IP to impede access to technologies in or for developing countries.
  - International development policy and knowledge and innovation policy are organizationally divided in two different ministries and generally perceived as two separate worlds.

A similar picture emerges from the analysis conducted in Uganda:

- IP knowledge among researchers and IP managers is low although it is evident that it is gradually increasing.
- IPR reforms are currently managed by institutions that are not directly mandated to support resource-poor farmers.
- The mandate over national IP policy is spread across agencies covering IP administration, trade and science and technology, often without robust coordination mechanisms.
- As a result, agricultural research managers and scientists do not have clearly defined policy platforms through which they can influence IP policy development to ensure that such policies are aligned to the needs of resource-poor farmers and the attainment of MDG 1.

- Most of the institutional policies that are currently in place are more inward-looking as they focus on the potential for the institutions and the scientists to benefit from IP protected innovations, rather than to benefit smallholder farmers.
- In the absence of effective institutional coordination, issues of access to agricultural technology by resource-poor farmers may be marginalized in the ongoing policy reform processes.

In South Africa, the existing IP policy and legal framework do include development considerations:

- The 2008 South African Intellectual Property Rights from Publicly Financed R&D Act established that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialized for the benefit of the people of South Africa, whether it be for a social, economic, military or any other national benefit.
- However, Clause 15 of the IPR Act dealing with determinations on intellectual property rights ownership with respect to co-financing of research and long-term research partnerships might deter private sector participation in research. The consequences of this clause need further investigation, but it is likely to lead to a decrease in private sector partnering with local R&D institutions, less contract research undertakings and fewer knowledge and technology transfer opportunities.

### 3.3 Compulsory Licensing is Difficult to Exploit

Although in theory compulsory licensing offers a legal solution to patent protection in relation to a range of MDG-related issues, in practice it appears difficult to exploit. The r**e**ports provide evidence of this as follows:

- The medical case study reveals that the flexibilities and safeguards available in the TRIPS Agreement and Doha Declaration are hardly being used by WTO member states.
- The analyses from Uganda show that Uganda has already drafted an IP legislation system but continues to find itself under international pressure to respect foreign IPRs at levels stronger than required by the TRIPS Agreement. This is also a major reason why compulsory licenses are hardly used.
- Although in theory compulsory licensing offers a legal solution to access patented technologies, for instance, HIV/AIDS treatment, in practice it is difficult to use compulsory licensing for the following further reasons:
    - Certain developed countries and large pharmaceutical companies have indicated that countries that issue compulsory licenses may face repercussions.[2]

[2] For instance, see Shirsat, M., (2011), pp. 9-12, referring to the cases of Brazil, Taiwan, and Thailand. Available at: <http://works.bepress.com/marcela_shirsat/1> (accessed 15 June 2011).

- Generic manufacturers are limited to producing only the quantities predefined in each compulsory license. This curbs the large-scale production that is required to deliver drugs cheaply.
- According to Article 31(f) of the TRIPS Agreement, compulsory licenses should be granted 'predominantly' to supply the 'domestic market', making it difficult to use regional solutions to manufacture needed supplies under a compulsory licensing scheme.
- A temporary waiver to the provision intended to help poor countries obtain needed drugs has not been made permanent and has hardly been used.

### 3.4 Private-Public Partnerships: a Mixed Blessing

The inability of the public sector to provide for the public good, lack of resources, inadequate infrastructure and inadequate human capacity have led to the emergence of private-public partnerships (PPPs). However, involvement of the private sector in public research turns out to be a mixed blessing. The sub-reports conclude the following as to the positive and negative sides of PPPs:

- PPPs, including governmental agencies, academic institutions, private industry, and not-for-profit organizations are being increasingly encouraged as part of the comprehensive socio-economic development framework and are proving to be an effective model for tackling, for instance, major public health and food security issues.
- Private sector partners offer public benefit though the provision of resources, technical expertise or outreach.
- A drawback of the involvement of the private sector in public research is that it may affect the conditions under which new university IP can be accessed by third parties. Usually, a company contributing to the research project obtains at least a right of first refusal to obtain a (non-)exclusive license for the technology in question, or an advantage of some years that information and materials will be withheld from others.
- Many companies have difficulties with the uncertainties that humanitarian use of IPRs may bring with them, especially also as compliance with their terms is difficult to control or enforce.
- Public research organizations take much care not to adversely affect the commercial interests of their private partners.
- There is often not a fair balance between the interests of the public and the private partners, in particular where the private partner is an international company and the public partner a local research organization. This is largely due to lack of negotiation skills with the public partners. Most striking is that local public partners often do not achieve rights on further development and pro-poor use.

## 4. The Need for IPRs for the Development, Transfer and Accessibility of Knowledge and Technologies for the Benefit of Sub-Saharan Africa

### 4.1 The Need for an Effective IP Protection System

Notwithstanding the abovementioned obstacles to knowledge transfer for development purposes created by the existing IPR systems, there is a clear need for an effective IP protection system in Sub-Saharan countries. A well-functioning IP system ideally enhances innovation and knowledge dissemination, provides protection needed to enter and to build markets, and facilitates compliance with and enforcement of IPRs. A potential obstacle to knowledge and technology absorption is in fact the lack of protection and subsequent exploitation of IP rights in many Sub-Saharan African countries:

- The two case studies (Part II and III) underline that there is a clear need for an effective IP protection system and point to the consequences of a weak (not enforceable) or deficient IP system:
  - A weak IP system may imply a lack of efficient innovation and knowledge dissemination systems. The duty to disclose calls for patent applicants to disclose all information that is material to the examination of the patent. Therefore, if the IP system is weak, then there would be limited disclosure of patent information and hence inefficient knowledge dissemination leading to inefficient innovation. In Uganda, for instance, where there is low internal patenting and plant variety protection, local scientists miss out on country specific knowledge that may be in existence but not recorded or systematized in any way. As a result, much-needed data that can assist the development of the country is not shared and disseminated.
  - The lack of an effective IP system in developing countries includes a lack of control and enforcement: this can make companies hesitant to accept the inclusion of humanitarian use clauses in license agreements as compliance with their terms cannot be easily controlled.
  - Above all, the lack of an effective IP system in developing countries implies a lack of adequate protection: this forms an (extra) impediment for companies to enter a market in developing countries, or to share their technologies with public and private research partners in these countries. Most companies from the "North" will only invest in developing country markets if they can protect their products from being copied, either by legal (e.g., IPRs) or technical means (e.g., hybrid seeds).
  - In the agricultural sector, to profit maximally from technical protection measures, companies in the "North" often will try to keep the production process secret – e.g., when producing hybrid seeds the parent lines will be kept secret. Another technological protection measure would be genetic use restriction technology (GURT), or 'terminator technology', which causes second generation seeds to be sterile.
  - The absence of legal protection by means of an effective IPR system may encourage private sector breeders to protect their interest through technical means which may seem undesirable in the light of the realization of MDG 1.

- With regard to the medical sector it was pointed out that the absence of protection also forms an impediment for African manufacturers to compete with non-African manufacturers. The inability of an African manufacturer to obtain an exclusive license prevents the African manufacturer from being protected from competition from abroad. Thus an African manufacturing base cannot be established.
- In the same case study it is also concluded that without commercial players being incentivised or provided some exclusivity (protection) to manufacture medical diagnostic technologies, it will be difficult to establish a medical diagnostics manufacturing industry in Sub-Saharan Africa.

## 4.2 Infrastructure as a Prerequisite for Generating and Absorbing IPR Protected Knowledge and Technology

The relationship between IPRs and development is complex. There can be a positive relationship in technologically advanced countries like South Africa that have high-level industries and manpower, while such a relationship cannot exist in less-developed countries in the absence of local use for a TRIPS-compliant system and functioning institutions.

In general, "infrastructure" could relate to: 1) policy infrastructure; 2) physical infrastructure; 3) legal infrastructure; 4) institutional infrastructure. Infrastructure is part of the enabling environment for both generating and absorbing IPR protected knowledge and technology. A basic, physical national infrastructure providing, *inter alia*, expertise, IT networks, and adequate laboratory equipment, is indispensable for generating national R&D output. National R&D in turn increases the ability to absorb new technologies. An IP- infrastructure includes an institutional, legal, and policy infrastructure, in which IPR awareness, capacity, and human resources for IPR management are guaranteed. Such IP-infrastructure is crucial for international research cooperation and effective technology transfer. However, the existence of a functioning IP-infrastructure (e.g., in the Netherlands) is not a guarantee for a pro-poor development orientation within the relevant IP-institutions and policies. Based on the sub-reports, the following observations emerge:

- Infrastructure is an oft-recurring theme in the context of IPRs. It is emphasised time and again that innovation cannot take place efficiently without a proper, comprehensive infrastructure. It is also argued by rights holders that the problems facing access to medicines in least developed countries have more to do with poor infrastructure (and barriers such as tariffs) than with IP rights.
- Sub-report 3 underlines that R&D institutions in Uganda are lacking basic, physical infrastructure. The project reveals that in the area of complex molecular testing protocols like HIV drug resistance testing, a major infrastructure related challenge concerns the need of laboratories for the expertise, equipment, reagents and consumables necessary to perform testing.
- Without resources, capacity and capability, R&D institutions in Uganda are unable to absorb new technologies or to carry out advanced research that can generate high volumes of R&D outputs including patents, publications and human resource expertise.
- It appears from the value chain-analysis with regard to agricultural products that in Uganda the awareness of IPRs by Ugandan research directors is low and that capacity

for IPR management is limited. Uganda also lacks critical human resources necessary to harness the existing flexibilities and exemptions in national and international legislation for the benefit of Ugandan resource-poor farmers.

- The sub-report on agriculture also notes that poorly framed institutional policies and the lack of knowledge of IPRs and their objectives create obstacles for international research cooperation and effective technology transfer. In such research environments foreign partners (public or private) either cannot operate or they take advantage of local conditions to misappropriate traditional knowledge.
- In the sub-report on agriculture it is further concluded that ideally, IP policy institutions must be able to work alongside agriculture R&D institutions, technology development, education institutions, and many others within such a system.
- As pointed out in the agriculture case study, Dutch ministries and research institutes have also failed to develop knowledge and policy with respect to the relationship between IPRs and the achievement of development objectives.
- In conclusion: the creation of a development-oriented IP infrastructure is also a matter of awareness, coordination and implementation and not merely funding.

## 5. Improving the Relationship between IPRs and Development

### 5.1 Introduction

The relationship between IPRs and the achievement of development objectives as formulated in MDG 1 ("Eradicate extreme hunger and poverty"; target 1c: "Reduce by half the proportion of people who suffer from hunger") and MDG 6 ("Combat HIV/AIDS, Malaria and other diseases") can be improved in two ways: mitigating the negative role played by IPRs (see 5.2) or, the other way round, enhancing their beneficial role (see 5.3). Mitigating the negative impact of IPRs on development objectives implies, first, addressing the obstacles mentioned in Section 2 of the synthesis, and second, giving the IP system a chance to rebalance by addressing the obstacles to the use of the pro-poor options in existing national and international IP legislation.

The enhancement of those aspects of the IP system that appear beneficial for the achievement of development objectives entails two things: at a practical level, the improvement of (IP and basic) infrastructure and, at a more fundamental level, (re-)opening the debate on the inclusion of development objectives and rules in national, regional and international IP systems.

### 5.2 Mitigating the Impact of IPRs on the Achievement of the MDGs

#### 5. 2.1 Addressing the Obstacles

Addressing the obstacles mentioned in section 2 of this synthesis – an unbalanced international IP system; overly optimistic perceptions regarding financial revenues of IPRs; the complexity of the IP landscape; limited development considerations at companies; several other aspects of IPRs having the potential to hamper pro-poor innovation – requires two steps: first, at a global and national level: taking the MDGs – and if not the MDGs as such, then the values they represent – as a *Leitmotiv* for future

research for development agendas, and, second, raising knowledge, awareness and expertise with regard to the relationship between IPRs and development at the regional, national and institutional level.

### 5. 2.1.1 Making Global Challenges – as Formulated in the MDGs – a *Leitmotiv* in Setting the National, Regional and International Research and Innovation Agendas

The sub-reports describe how the "power differential" – the difference in strength, influence and participation between "North" and "South" – has resulted in developed countries dominating the entire process from negotiating the international IPR regime to applying the rules largely as they see fit. As a result, development priorities and objectives have not been a prominent aspect of international IP lawmaking and are playing only a subsidiary role in the implementation of IPRs at the national level. Thus, the "power differential" has led to an international IP system that is not well prepared to fulfill its central role in balancing private *and* public interest at a global level – thus, the interests of the developed world with the interests of developing world (as reflected in the MDGs for example). The imbalance in the international IP system, caused by the power differential, appears to be the underlying cause of most obstacles to pro-development sharing of knowledge and technology mentioned. In order to rebalance the international IP system, more synergy should be created between IP policies and development. Global challenges – as formulated in the MDGs – should become the focal point in setting the international, regional, national and institutional research and innovation agendas. From the sub-reports can be deduced that in order to achieve this:

- It is important that individual developing states are not being forced but rather encouraged to have direct input into national, regional and international IPRs.
- National legislation governing IP should have a clear development orientation. So far, national legislation in Sub-Saharan countries has been drafted as a result of assistance from WIPO and growing capabilities of OAPI and ARIPO. While the desired outcome of this assistance is standardizing, harmonizing and building of IP protection and management tools for Africa, a clear focus on the, regional, national, and local development needs is often missing. For instance, on the one hand, by strengthening African information clearinghouses[3] that provide information on patents filed in Africa, IP can be better managed within the continent, but on the other hand opportunities are removed for African countries to shape IP rights to their national needs. This is particularly visible in the promotion of the UPOV system for breeder's rights which bypasses needs of smallholder farmers.
- WIPO's technical assistance programs must make sure that they include an adequate development orientation in conformity with the WIPO Development Agenda[4].
- As regards the Netherlands, more synergy should be created between the till now organizationally divided worlds of international development policy and research and innovation policy. As advised by the Advisory Council for Science and Technology Policy (AWT), the Dutch government should make global challenges a *Leitmotiv* in setting the national research and innovation agenda.

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3 See Annex III.

4 <http://www.wipo.int/ip-development/en/agenda/recommendations.html> (accessed 15 June 2011).

- One solution to consider – applied by the Dutch Directorate-General of International Cooperation (DGIS) – in order to secure the availability for development purposes of research outcomes is to keep co-ownership and therefore a say over the IP resulting from the research it finances.

#### 5.2.1.2 Increasing Knowledge, Creating Awareness and Building Expertise with regard to the Impact of IPRs on the Achievement of Development Objectives at the National, Regional and Institutional Levels.

The problem of the widespread lack of knowledge, awareness, and expertise as to the role of IPRs in the context of transfer of knowledge and technology development purposes can in fact be addressed only by building more expertise and enhancing dissemination of knowledge at the institutional and national, regional as well as international levels. According to the sub-reports

- More awareness and knowledge should be raised about the functioning of IPRs in general, and about their functioning in a development context in particular. There is a widespread lack of awareness as regards the relationship between IPRs and development in both developing countries such as Uganda, as well as developed countries such as the Netherlands.
- More knowledge and expertise will lead to more realistic perceptions and temper high expectations regarding financial revenues from IPRs. This, in turn, might lead to more confidence in the use of pro-development options in existing IP instruments.
    - The rights of breeders and privileges of farmers should be carefully balanced, and suitable incentives should be created for commercial sub-sectors in agriculture in developing countries while avoiding negative impact on resource-poor farmers.
- Creating awareness and knowledge of the effect of patents and in particular of the impact of restrictive IP policies (restrictive licensing, restrictive MTAs, blocking patents) on development objectives might increase socially responsible behavior and policies of companies and research institutions:
    - In order to mitigate the distorting effect of IPRs on, for instance, food security, it is crucial to acknowledge the role of informal seed systems alongside the formal seed system.
    - An important role and responsibility for international research agencies and donors investing in agricultural research is to provide safeguards for access to new varieties.
- The IP landscape both in medical diagnostics as well as biotechnology is highly technical and complex. Consequently, a comprehensive FTO analysis requires expertise and resources.
- The role of TTOs is critical in facilitating transfer of information from international public and private partners to commercial partners within developing countries; particular focus should be given to how to assist and develop TTO capacity to accomplish this.

### 5.2.2 Addressing Obstacles to the Use of Pro-development Options in Existing National, Regional and International IP Legislation.

The failure to use the existing pro-development options in existing national, regional and international IP legal instruments could be attributed to the following obstacles: Inadequate national legislation, a lack of development considerations in IP policies in developing as well as developed countries, difficulties encountered with the exploitation of compulsory and humanitarian licensing, and some imbalances in research cooperation within public-private partnerships.
Addressing these obstacles will, as partially suggested in the foregoing paragraph, boil down to the following measures:

- Draft or revise national legislation with a clear development orientation.
- Increase knowledge of Dutch, Ugandan and South African stakeholders concerning the relationship between IPRs and the achievement of development objectives.
- Create awareness with all stakeholders, including companies and agricultural research centres, both in the Netherlands, South Africa and Uganda, concerning their social responsibility.
- Build effective and coordinated IP institutions in developing countries and make sure they include an adequate development orientation.

## 5.3 Harnessing IPRs to Achieve Development Objectives

IP protection is an instrument to stimulate and balance private and public interests in research and innovation. As such, IP is an instrument that could be harnessed to achieve clearly defined development objectives. On a practical level, this entails the improvement of basic as well as specific IP infrastructure in developing as well as developed countries. On a more fundamental level, this means a (re-)opening of the discourse on the inclusion of development considerations in national and international IPR policies.

### 5.3.1 Improvement of Infrastructure

As mentioned above, infrastructure is part of the enabling environment for both generating and absorbing IPR protected knowledge and technology. A basic, physical national infrastructure is indispensable for generating national R&D output. Such infrastructure entails expertise, IT-networks and adequate laboratory equipment. (Again see above.) The solutions proposed in the sub-reports can be seen as mirror images of the problems described above:

- Investments in legal institutions as well as education and awareness-raising on a professional and academic level, with a focus on specific IPR elements and on the political and organizational contexts within which IPRs have to function.
- One needs to work, systematically on capacity building on managerial and non-managerial levels concerning all aspects of the IPR that are problematic, in a way that leads to sustainable self-supportiveness.

- Awareness that 'infrastructure' is linked to specific requirements as well, for instance, laboratories and medical equipment, or agricultural machinery adapted to local situations.
- Designing adequate institutional policies and tackling the lack of knowledge of IPRs in order to remove obstacles for further research and for international research cooperation in order to enhance access to evidence-based best practices and solutions.
- Ideally speaking, government departments responsible for IP policy must be able to work alongside R&D institutions, technology development and dissemination institutions, IP regulatory agencies and many others within one coherent system. At minimum, they should know and understand one another. So far, many actors are operating separately and remotely. This goes for developing as well as developed countries.
- As stated at the end of Paragraph 4.2: the creation of a development-oriented IP infrastructure is also a matter of awareness, coordination and implementation and not just funding. Awareness of the legal technicalities and the underlying values – given this project, as incorporated in the MDGs, especially 1 and 6 – comes first, followed by actual knowledge and expertise. Financial investments will then (have to) follow, either because they are profitable from an economic point of view or because they are seen as mandatory from a societal perspective.

### 5.3.2 Re-opening the IP Policy Discourse

As such, IP is an instrument that could be harnessed to achieve clearly defined development objectives. Whether development considerations will actually be included in national, regional, and international IP policies is ultimately a matter of political will and political decision-making. As shown in this project, these (non-)decisions are too often based on false perceptions, unrealistic expectations, insufficient knowledge, and a lack of awareness and public responsibility.

The MDGs – symbolizing global awareness of and determination to address a series of global challenges – provide a new context and add new responsibilities and opportunities to the political decision-making arena. Eventually, the MDGs and the global challenges and values they embody might provide the weight needed to re-balance the international IP system. The following arguments and building blocks can be taken from the reports:

- The IP policy discourse has two sides that have to be kept in mind: (a) Proponents of substantive and tighter harmonisation of national IP systems to meet the needs of current IP rights holders operating globally. (b) Others who maintain that national IP systems should be customised to meet local needs and interests, including through the use of TRIPS-compliant flexibilities, or even beyond these flexibilities.
- The latter view implies that technical assistance should focus on fostering the ability of national governments and stakeholders to adjust the IP system to the needs of individual developing countries, with a focus on elements such as institutions for technology transfer, compulsory and humanitarian licensing regimes, and countering anti-competitive behavior by IP rights holders.
- Sub-Saharan African countries have to find a way to accommodate both approaches:

  - While the ongoing IP policy process in many African countries is largely anchored within the global discourse regarding compliance with the TRIPS agreements, they emphasise the need for greater support for local companies, scientists, and artists to make use of the IP system to boost local development and protect their own inventions and creations on the international market.
  - It is concluded in the agricultural sub-project that the utility of IP can only be felt if a country focuses on how to harness this instrument to achieve clearly defined national development objectives, and that, therefore, a meaningful IP policy discourse should be anchored in the overall development discourse of the country.
- The perspective of developing countries is gaining momentum in the international IPR debate, as also visible in the global and national development agendas. More and more evidence is emerging that the system as it is favors industrialized countries over developing countries, which is no longer accepted.
- There is no consensus, however, on whether or not to change the international IPR system and how. Allowing and assisting developing countries to make better use of the already existing "flexibilities" in the international IPR system might bring relief on relatively short notice, but should not lead to closing eyes on the need for structural revisions of the global IPR system and its interaction with and relevance for regional, national and local African needs. Action is required on different levels.

## CONCLUDING REMARKS

IPRs are basically national legal instruments designed to balance the rights of inventors with those of society at large. They can be described as time-limited legal exclusionary rights. As regards patents, in exchange for public disclosure of an invention, inventors are permitted, for a limited time, the sole right of exploitation before it enters the public domain and all others are free to manufacture, use, sell or offer to sell, improve or develop it. In the global context of the development needs of (Sub-Saharan) Africa and trade interests of the developed world this balance has been upset. However, at the start of the new millennium, the MDGs provided a new context and added new responsibilities for the global community, presenting an opportunity for IPRs to resume their initial role as an international instrument for balancing private interests *and* (global) public interests. The three studies make clear that harnessing IPRs for development objectives is a cumbersome process.

Sub-project 1 reveals the core causes and the consequences for Sub-Saharan Africa of an unbalanced international IPR system. It describes, amongst other things, how the TRIPS implementation process in Africa has been motivated by the protection of the IP originating in developed states rather than as an instrument for innovation, competition and economic development in Africa. Further to that, it shows how developing countries, in order to be TRIPS compliant, and later sometimes even TRIPS-plus compliant, have been pushed – although some countries were eager – to modify, and in some cases significantly alter, their legislation, legal systems and IPR administration. Next to this, sub-project 2 shows a discouraging picture ranging from IPRs distorting local food supply systems to a near-complete lack of development awareness and considerations in IP policies and legislation in both the "North" and in the "South". Against this background, it shows that IPRs appear to be

relevant for development purposes only where they provide flexibilities, exceptions and pro-development options, or where the international system leaves sufficient room for countries to adjust global standards to meet the realities of domestic conditions. Sub-project 3, finally, demonstrates the (possible) benefits of a well-functioning IPR system and underlines its importance for innovation and commercialization of medical devices in South Africa. At the same time, the outcomes of this sub-project reveal the problems in achieving such a well-functioning IPR system. Those problems are often related to the lack of various forms of infrastructure.

From each of the sub-reports it appears that most obstacles to sharing knowledge for development purposes can be traced back to the imbalances in the IPR systems, especially on the international level. The system by and large focuses on private interests and potential economic revenues of IPRs and neglects the importance of knowledge and technology transfer for public interests, like the realization of development objectives. In order to re-balance the international IP system, more synergy has to be created between IP policies and development policies, on all levels, putting challenges and values as incorporated in the MDGs in the lead. Such a shift in standard- and agenda-setting should also relate to the required (but mostly lacking) IP infrastructure in African and Western countries: a shift from a classical IP infrastructure to an 'IP-for-development-infrastructure' consisting of knowledge, awareness, and expertise as to the role of IPRs in the context of transfer of knowledge and technology for development purposes. The building of this latter form of infrastructure will minimize obstacles to the use of the existing pro-development options and exemptions in existing IP laws and treaties. However, in the longer run, such an 'IP-for-development-infrastructure' will change the international IP system from within. Development objectives will no longer be framed as 'options', 'exemptions' or 'clauses', but will be recognized as part of the IP system itself: the *public interest* side of the balance.

# RECOMMENDATIONS

## 1. Introduction

Whereas a well-functioning national infrastructure is indispensable for generating R&D output on the national level in countries with an advanced research environment, a balanced international IP infrastructure is crucial for international research cooperation and effective technology transfer between and towards developing countries. The role of IP in technologies reaching poor farmers/consumers requires careful consideration. In previous sections of Part IV of the report the core elements of such an 'IP-for-development infrastructure' have been synthesized extensively. In the paragraphs to come, they are followed by recommendations addressed to the core actors in the field. The recommendations are structured along different geographical levels: the global level (WTO, WIPO and UPOV; par. 2), the regional level (ARIPO and OAPI; par. 3), the national level of Sub-Saharan African states, and the Netherlands (par. 4). Finally, recommendations are addressed to development partners (donors) universities, research institutions and companies with research agendas and capacities relevant from an MDG perspective (paras. 5 and 6).

## 2. Global Level (WTO, WIPO, and UPOV)

As to the global level (WTO, WIPO, and UPOV), the report leads to the following recommendations:

- In general, all three organizations:
  - Allow and support developing countries – if not possible within the existing treaties by amending the treaties – to set up diverging and tailor-made IP policies and systems, addressing their core development needs, as expressed in the context of the MDGs, especially MDG Nos. 1 and 6.
  - Address the need for the development of institutions and strategies that seek to facilitate the acquisition and further development of technologies required for research and development relevant to meeting the MDGs.
  - Specifically in the field of health: create a global funding mechanism for IPRs concerning public health, to go beyond the call of treating disease symptoms and focus on building capacity in health research and development.

- WTO:
  - In the longer run: revise the TRIPS Agreement. The context of the TRIPS Agreement is biased towards the economic interests of the developed countries. Therefore, there is a clear need for a fundamental revision of TRIPS with a fair balance between the interest of all countries.
  - For the time being: adapt and use the TRIPS flexibilities to meet African development needs and draft them in a way that ensures access to medicines and the fulfilment of human rights obligations of African states under core international and regional human rights treaties.

- Encourage, support and assist African states to utilize maximally the 2001 Doha Declaration on the TRIPS Agreement and Public Health. The waiver formulated in this declaration permits the exportation of more medicines produced under compulsory license to those countries that lack sufficient manufacturing infrastructure to produce these medicines for themselves.

- WIPO:
  - Take into account the perspective and infrastructural context of the African states as well as their development needs more explicitly than has been the case so far, while providing assistance to African countries with regard to draft legislation, using patent information, awareness drives, et cetera.
  - Evaluate the functioning of the current international patent system on a global level, in particular from the perspective of developing countries versus the perspective of developed countries.
  - Fully implement the 45 recommendations of the 2007 WIPO Development Agenda.
  - Develop potential mechanisms to curtail the use of blocking patents with regards to strategic patenting.

- UPOV:
  - Investigate the expansion of the 'private and non-commercial use' exemption in Plant Breeder's Rights to all resource-poor farmers, in order to enable them to exchange seed among their peers.
  - Investigate the need and consequences of including a breeder's exemption in patent law.
  - Develop international IPR and regulatory policies with respect to generic competition in agricultural biotechnology now that the first GM technologies will come off patent (See Box II-20).
  - Investigate opportunities to more clearly focus seed policies, and thus also variety protection levels on the different 'agricultures' in each country, as currently promoted by the African Union Commission.
  - Include MDG-relevant aspects in the negotiations towards a modernized UPOV Conference to replace its 1991 Act.

### 3. Regional Level (ARIPO and OAPI)

As to the regional level (ARIPO and OAPI), the report leads to the following recommendations, for both organizations simultaneously:

- In keeping a focus on development objectives also take the MDGs into consideration. ARIPO and OAPI should provide clear guidance to governments, public researchers and industry, encouraging innovation, trade and investment and promoting technology transfer (1) to benefit local manufacturers and farmers and (2) to harness nationally and locally generated IP for social and economic development.
- Develop an autonomous vision on IPRs and development needs in Africa and draft an African IP policy based on this vision.

- Consider the development of an African Patent Organization to create an efficient and harmonized regional patent system tailor-made to the specific needs of Africa. It should be noted however that the African Union has adopted Africa's Science and Technology Consolidated Plan of Action. The implementation of this Plan of Action includes establishment of the Pan African Intellectual Property Organization (PAIPO). PAIPO is intended to be the EPO equivalent in Africa. However, it is not clear at this stage what will happen to ARIPO and OAPI once PAIPO is created.[5]

## 4. National Level

### 4.1 African Governments

The two African countries specifically studied in this project – South Africa and Uganda – represent quite different levels of industrial development and have significant differences in their absorptive capacity for technology and differing levels of capacity to innovate. Uganda is classified by the United Nations as a least developed country (LDC), with different opportunities and challenges with respect to IP, as opposed to South Africa which is regarded as a developing or middle developing country. The following recommendations will be relevant for most African LDCs and, to some extent, also for South Africa. Some specific recommendations for South Africa have been formulated at the end of this section. As to African governments, the report leads to the following recommendations:

- Keep a focus on development objectives. National IP policies should provide clear guidance to public researchers and industry, encouraging innovation, trade and investment and promote technology transfer to (1) benefit local companies and local manufacturers, and to (2) harness locally generated IP for social and economic development, including contributing to the MDGs.
- Create a coordination mechanism for national IP policies, linking together agencies covering IP administration, trade, and science and technology.
- Prioritize and establish a public research agenda. Such an agenda should identify priority research areas, locate funding sources and determine desired research output. This should coordinate research activities so as to optimize the available research capacity and avoid ineffective duplication of effort, for example with the private sector.
- Develop policies with relevance on the ground. In states with a low level of innovation output, the IP policies need to have relevance on the ground rather than to remain theoretical frameworks that have little application to those for whom they have been created.

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5 Human Resources, Science and Technology, Extraordinary Conference of the African Ministers of Council on Science and Technology (Amcost), 20 – 24 November 2006, Cairo, Egypt. A Concept Paper: Establishing a Pan-African Intellectual Property Organization, (Paipo).

- Develop coherent IP policies with respect to public research with attention to access to technology for development purposes, such as humanitarian use licenses, open access publishing, and a broad interpretation of research exemptions for medical and agricultural uses.
- Build expertise and capacity. Adequate human resource capacity and capability is needed for policy implementation. Invest in experts able to develop, interpret and apply the IP policies correctly across sectors such as academia, industry, the judiciary system, trade and enforcement.
- Share the governmental public research strategies with the donor community for them to understand the country's strategic research priorities; be more proactive in influencing donor investment and give them an opportunity to contribute to the implementation of the strategies.
- Better use the existing pro-development IPR options. While developing national IP laws, include in these national statutes as many of the flexibilities and safeguards available in the TRIPS Agreement and Doha Declaration which promote the national interest; do not include provisions that go beyond the requirements of the TRIPS Agreement (such as the "TRIPS-plus" provisions).

Specifically in the field of agriculture:

- Evaluate and reconsider the institutional policies of African research institutions in the field of agriculture that are currently in place and which focus on the potential for the institutions and the scientists to benefit from IP-protected innovations, not just for monetary revenues.
- Adopt policy instruments that explicitly articulate the need to use IP to direct agricultural research to address the technology needs of resource-poor farmers.
- Create policy platforms to make sure that agricultural research managers and scientists can influence IP policy development to ensure that such policies are aligned with the needs of resource-poor farmers and the attainment of MDG 1.
- Be aware of the fact that African agricultural research institutions face a multiplicity of challenges, which in many cases make them less effective in fulfilling their public research mandate. There is an important role for African governments to provide funding to overcome challenges like this.
- Develop other mechanisms for funding, such as the generation of revenues from innovations, through modest licenses. Public funding has either been declining or has remained unchanged even when the need for agricultural research has continued to expand in the face of major problems such as new pests and diseases, drought and climate change as well as post-harvest losses.

Specifically in the field of health:

- With fragile health research and health services infrastructures it is necessary to create market incentives to support health innovation, generate access to and local production of essential medicines.
- Include an appropriate exception for "early working" to patent rights ("Bolar exception") in legislation, which will accelerate the introduction of generic substitutes on patent expiry.

Specifically as to South Africa:
Unlike many other African states, South Africa has a relatively advanced IP system, has gained considerable experience in managing IP derived from public and private R&D activity, has a relatively good public R&D infrastructure and resources, and has manufacturing capacity and capability. As a result, South African institutions are often able to establish sophisticated IP management strategies designed to overcome barriers to access to technologies and facilitate the exchange of knowledge and technologies between local and international researchers. Several specific recommendations have been formulated for the South African government:

- Support further health research in South Africa. While the scale of health research in South Africa remains small relative to developed countries, it is significant when compared to the rest of Africa. Health research into HIV/AIDS, malaria and tuberculosis is widespread within the country and important results to combat these diseases are being generated.
- Encourage more South-South interactions within the African continent to fast track knowledge and technology transfer and contribute to improving other research and production facilities in Africa.
- Use and strengthen the capability to manufacture antiretroviral generics for use locally and elsewhere in Africa.
- Accelerate the development of a competitive generics manufacturing industry in order to accelerate access to HIV/AIDS drugs and health innovations.
- Ensure, for instance by subsidizing, that the drugs manufactured are of high quality and do not cost more than those produced in countries like India and Brazil.
- Monitor and evaluate the South African research output in order to find out why South Africa's patenting and publication rates are declining.
- Consider an amendment to the IPRs from Publicly Financed R&D Act to encourage private sector participation in research.
- Provide incentives to encourage private industry to invest in the establishment of new manufacturing enterprises for the production of medical diagnostic products.

### 4.2 The Government of the Netherlands

As to the government of the Netherlands, the report contains the following recommendations:

- Include provisions in the Dutch Patent Act to promote humanitarian licenses and other provisions relevant to development in order to respond to international obligations under, i.a., TRIPS Article 66.2; the MDG's; CBD.
- Develop a coherent IP policy with respect to public research and public research funding with attention to access to technology for development purposes, such as humanitarian use licenses, open access publishing, and a broad interpretation of research exemptions for medical and agricultural uses.
- Include pro-development IP provisions in research funding agreements.
- Evaluate the current research funding system with regard to the development orientation of basic funding, co-matching, and funding conditions that relate to IP.

- Develop criteria and incentive mechanisms for valorization that go beyond mere outputs for the Dutch economy and reach across borders.
- Develop clear criteria that can evaluate and value non-economic results and applications of public research and can create a context in which international development outputs can be recognized and stimulated.
- Build more expertise and capacity with respect to humanitarian licensing strategies at public research organizations and funding agencies.

### 5. Development Partners (donors)

- Actively support technology transfer as called for in TRIPS and several other international agreements (such as the Convention on Biological Diversity).
- While supporting international and national research organizations, include development language in the contracts with those research organizations to make sure that the poor have maximum access to the results of such research.
- Support capacity building to rectify knowledge gaps between northern and southern partners with respect to IPRs.
- Actively oppose patents that obstruct development goals.

### 6. Universities, Research Institutes and Companies with Research Programs

As to universities and other research institutions as well as companies with research programs and capacities relevant from an MDG perspective, the report contains the following recommendations:

### 6.1 African Institutions and Companies

- Try to increase the consistency in the manner in which international research partnership agreements both with public and private international partners approach the issue of IP. This apparent gap provides a tremendous opportunity for African agricultural and other research institutions to shape the content of institutional IP policies to ensure that they reflect their research for public goods mandate.
- Grasp the opportunities created by the low rate of foreign patenting in Sub-Saharan Africa. The low number of foreign entities patenting (for instance in Uganda) gives the opportunity to access patented medical and agricultural technologies and research technologies and tools to benefit its own R&D activity and any pharmaceutical and agricultural manufacturing potential that exists.
- Ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income of the licensor. This might be a difficult task for companies that need to maximize profit in order to survive. For public research organizations it is easier to have different goals.
- Monitor and evaluate R&D outputs. This ensures that R&D remains relevant to the health and agricultural needs of the countries and allows tracking of a country's and funder's return on investment. It allows for identifying more efficient and productive areas and national strengths.

- Increase IP knowledge among researchers and IP managers, especially about pro-development IP options, such as open source licensing models.
- Create awareness among researchers and IP managers of the relation between IP and the achievement of development objectives.
- Encourage IP managers and researchers within research institutions to be more proactive and ensure that the policies adopted conform to their mandate to produce goods for the benefit of resource-poor farmers.
- Introduce incentive models that will encourage local R&D institutions to increase their R&D output.
- As to IP management capacity:
  - Identify critical IP training needs, such as the ability to perform FTO analysis prior to technological research and development.
  - Provide training in the area of IP and development, including introduction of IP management strategies, policies and processes and procedures at the institutional level, and ways for imparting knowledge and expertise to fellow colleagues and decision-makers in government and R&D institutions.
  - Include training in the area if IP and development in curricula for students of law, science, engineering, business, political science, et cetera.
  - Invest in developing the capacity and expertise at institutional technology transfer offices (TTOs), the role of TTOs having been identified as crucial in IP management in developing countries.
  - Be aware that management of IP in itself also requires significant resources over and above those needed for technological research and development, and budget accordingly.
  - Provide for funding of TTOs and take away pressure on TTOs to become profitable, and guide them by appropriate institutional strategy and direction in this regard. These measures will allow them to focus on broader social objectives rather than seeing IP rights only as institutional income generators.
  - Involve TTOs in the development, the finalisation and the management of effective consortium agreements for the relevant institutions.
  - Appoint an IPR TTO agreements manager for such consortia that can review agreements in the overall context of the consortia.
  - Take care that TTOs of consortium members have legal expertise to be able to interpret legal clauses and their meanings in the various agreements.

### 6.2 Dutch Research Institutions, Technology Transfer Institutes, and Companies

- Develop criteria and incentive mechanisms for valorization that go beyond mere outputs for the Dutch economy and reach across borders.
- Adopt and implement policies that conform to their mandate to produce public goods.
- Ensure that research priorities, particularly as regards the technology requirements of the poor, be it in agriculture or health, are not distorted by the search for a larger licensing income of the licensor.
- Increase awareness among researchers of the potential impact of IP on the achievement of development objectives.

- Increase knowledge of IP among researchers and IP managers with attention to instruments allowing access to technology for development purposes, such as humanitarian use licenses, open access publishing, and open source.
- Link with pro-development international initiatives (e.g., Global Access in Action) and develop a clear IP policy in this area.
- Monitor and evaluate R&D outputs in a broader sense to ensure that R&D promotes global public goods. Build IP management capacity:
    - Identify critical IP training needs and select dynamic individuals for training on IP in the medical/agricultural R&D field. One such need identified concerns the ability to perform FTO analysis prior to technological research and development.
    - Invest in developing the capacity and expertise at institutional technology transfer offices (TTOs), the role of TTOs having been identified as crucial in IP management in also developed countries.
    - Provide for funding and take away pressure on TTOs to become profitable, and guide them by appropriate institutional strategy and direction in this regard. These measures will allow them to focus on broader social objectives rather than seeing IP rights only as institutional income generators.

# ANNEX: Official list of MDG indicators[1]

**All indicators should be disaggregated by sex and urban/rural as far as possible.**

***Effective 15 January 2008***

| Millennium Development Goals (MDGs) | |
|---|---|
| **Goals and Targets (from the Millennium Declaration)** | **Indicators for monitoring progress** |
| **Goal 1: Eradicate extreme poverty and hunger** | |
| Target 1.A: Halve, between 1990 and 2015, the proportion of people whose income is less than one dollar a day | 1.1 Proportion of population below $1 (PPP) per day[i]<br>1.2 Poverty gap ratio<br>1.3 Share of poorest quintile in national consumption |
| Target 1.B: Achieve full and productive employment and decent work for all, including women and young people | 1.4 Growth rate of GDP per person employed<br>1.5 Employment-to-population ratio<br>1.6 Proportion of employed people living below $1 (PPP) per day<br>1.7 Proportion of own-account and contributing family workers in total employment |
| Target 1.C: Halve, between 1990 and 2015, the proportion of people who suffer from hunger | 1.8 Prevalence of underweight children under-five years of age<br>1.9 Proportion of population below minimum level of dietary energy consumption |
| **Goal 2: Achieve universal primary education** | |
| Target 2.A: Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling | 2.1 Net enrolment ratio in primary education<br>2.2 Proportion of pupils starting grade 1 who reach last grade of primary<br>2.3 Literacy rate of 15-24 year-olds, women and men |
| **Goal 3: Promote gender equality and empower women** | |
| Target 3.A: Eliminate gender disparity in primary and secondary education, preferably by 2005, and in all levels of education no later than 2015 | 3.1 Ratios of girls to boys in primary, secondary and tertiary education<br>3.2 Share of women in wage employment in the non-agricultural sector<br>3.3 Proportion of seats held by women in national parliament |
| **Goal 4: Reduce child mortality** | |
| Target 4.A: Reduce by two-thirds, between 1990 and 2015, the under-five mortality rate | 4.1 Under-five mortality rate<br>4.2 Infant mortality rate<br>4.3 Proportion of 1 year-old children immunised against measles |
| **Goal 5: Improve maternal health** | |
| Target 5.A: Reduce by three quarters, between 1990 and 2015, the maternal mortality ratio | 5.1 Maternal mortality ratio<br>5.2 Proportion of births attended by skilled health personnel |
| Target 5.B: Achieve, by 2015, universal access to reproductive health | 5.3 Contraceptive prevalence rate<br>5.4 Adolescent birth rate<br>5.5 Antenatal care coverage (at least one visit and at least four visits)<br>5.6 Unmet need for family planning |
| **Goal 6: Combat HIV/AIDS, malaria and other diseases** | |
| Target 6.A: Have halted by 2015 and begun to reverse the spread of HIV/AIDS | 6.1 HIV prevalence among population aged 15-24 years<br>6.2 Condom use at last high-risk sex<br>6.3 Proportion of population aged 15-24 years with comprehensive correct knowledge of HIV/AIDS<br>6.4 Ratio of school attendance of orphans to school attendance of non-orphans aged 10-14 years |

[1] Source: < http://mdgs.un.org/unsd/mdg/Host.aspx?Content=Indicators/OfficialList.htm >.

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| Target 6.B: Achieve, by 2010, universal access to treatment for HIV/AIDS for all those who need it | 6.5 Proportion of population with advanced HIV infection with access to antiretroviral drugs |
| Target 6.C: Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases | 6.6 Incidence and death rates associated with malaria<br>6.7 Proportion of children under 5 sleeping under insecticide-treated bednets<br>6.8 Proportion of children under 5 with fever who are treated with appropriate anti-malarial drugs<br>6.9 Incidence, prevalence and death rates associated with tuberculosis<br>6.10 Proportion of tuberculosis cases detected and cured under directly observed treatment short course |
| **Goal 7: Ensure environmental sustainability** | |
| Target 7.A: Integrate the principles of sustainable development into country policies and programmes and reverse the loss of environmental resources<br><br>Target 7.B: Reduce biodiversity loss, achieving, by 2010, a significant reduction in the rate of loss | 7.1 Proportion of land area covered by forest<br>7.2 CO2 emissions, total, per capita and per $1 GDP (PPP)<br>7.3 Consumption of ozone-depleting substances<br>7.4 Proportion of fish stocks within safe biological limits<br>7.5 Proportion of total water resources used<br>7.6 Proportion of terrestrial and marine areas protected<br>7.7 Proportion of species threatened with extinction |
| Target 7.C: Halve, by 2015, the proportion of people without sustainable access to safe drinking water and basic sanitation | 7.8 Proportion of population using an improved drinking water source<br>7.9 Proportion of population using an improved sanitation facility |
| Target 7.D: By 2020, to have achieved a significant improvement in the lives of at least 100 million slum dwellers | 7.10 Proportion of urban population living in slums[ii] |
| **Goal 8: Develop a global partnership for development** | |
| Target 8.A: Develop further an open, rule-based, predictable, non-discriminatory trading and financial system Includes a commitment to good governance, development and poverty reduction – both nationally and internationally<br><br>Target 8.B: Address the special needs of the least developed countries<br>Includes: tariff and quota free access for the least developed countries' exports; enhanced programme of debt relief for heavily indebted poor countries (HIPC) and cancellation of official bilateral debt; and more generous ODA for countries committed to poverty reduction<br><br>Target 8.C: Address the special needs of landlocked developing countries and small island developing States (through the Programme of Action for the Sustainable Development of Small Island Developing States and the outcome of the twenty-second special session of the General Assembly)<br><br>Target 8.D: Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term | *Some of the indicators listed below are monitored separately for the least developed countries (LDCs), Africa, landlocked developing countries and small island developing States.*<br><br><u>Official development assistance (ODA)</u><br>8.1 Net ODA, total and to the least developed countries, as percentage of OECD/DAC donors' gross national income<br>8.2 Proportion of total bilateral, sector-allocable ODA of OECD/DAC donors to basic social services (basic education, primary health care, nutrition, safe water and sanitation)<br>8.3 Proportion of bilateral official development assistance of OECD/DAC donors that is untied<br>8.4 ODA received in landlocked developing countries as a proportion of their gross national incomes<br>8.5 ODA received in small island developing States as a proportion of their gross national incomes<br><u>Market access</u><br>8.6 Proportion of total developed country imports (by value and excluding arms) from developing countries and least developed countries, admitted free of duty<br>8.7 Average tariffs imposed by developed countries on agricultural products and textiles and clothing from developing countries<br>8.8 Agricultural support estimate for OECD countries as a percentage of their gross domestic product<br>8.9 Proportion of ODA provided to help build trade capacity<br><u>Debt sustainability</u><br>8.10 Total number of countries that have reached their HIPC decision points and number that have reached their HIPC completion points (cumulative)<br>8.11 Debt relief committed under HIPC and MDRI Initiatives<br>8.12 Debt service as a percentage of exports of goods and services |

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| Target 8.E: In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries | 8.13 Proportion of population with access to affordable essential drugs on a sustainable basis |
| Target 8.F: In cooperation with the private sector, make available the benefits of new technologies, especially information and communications | 8.14 Telephone lines per 100 population<br>8.15 Cellular subscribers per 100 population<br>8.16 Internet users per 100 population |

The Millennium Development Goals and targets come from the Millennium Declaration, signed by 189 countries, including 147 heads of State and Government, in September 2000 (http://www.un.org/millennium/declaration/ares552e.htm) and from further agreement by member states at the 2005 World Summit (Resolution adopted by the General Assembly - A/RES/60/1, http://www.un.org/Docs/journal/asp/ws.asp?m=A/RES/60/1). The goals and targets are interrelated and should be seen as a whole. They represent a partnership between the developed countries and the developing countries "to create an environment – at the national and global levels alike – which is conducive to development and the elimination of poverty".

[i] For monitoring country poverty trends, indicators based on national poverty lines should be used, where available.

[ii] The actual proportion of people living in slums is measured by a proxy, represented by the urban population living in households with at least one of the four characteristics: (a) lack of access to improved water supply; (b) lack of access to improved sanitation; (c) overcrowding (3 or more persons per room); and (d) dwellings made of non-durable material.

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**Bijlage(n)**
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Datum 18 maart 2011
Betreft Focusbrief ontwikkelingssamenwerking

Hierbij stuur ik u de Focusbrief ontwikkelingssamenwerking. Deze brief bevat, zoals aan u toegezegd, een uitwerking van de Basisbrief Ontwikkelings-samenwerking.

Leidraad van deze notitie is het maken van keuzes, vooral in het bilaterale deel van internationale samenwerking. Deze keuzes betreffen de speerpunten van beleid en de landen waarmee Nederland een intensieve bilaterale ontwikkelingsrelatie nastreeft.

De Staatssecretaris van Buitenlandse Zaken,

Dr. B. Knapen

# Focusbrief ontwikkelingssamenwerking

## I Inleiding

De drie belangrijkste doelen van het buitenlandse beleid zijn het verbeteren van de economische positie van Nederland in de wereld, het bevorderen van stabiliteit en veiligheid in de wereld, en het bevorderen van mensenrechten en rechtsstaat.

Om resultaten te boeken, moet Nederland samenwerken. Ook met ontwikkelingslanden, omdat zij zowel deel zijn van het probleem als van de oplossing. De armoede in ontwikkelingslanden en de Nederlandse doelstellingen hangen nauw met elkaar samen. Het is de kunst om belangen bij elkaar te brengen. Ontwikkelingssamenwerking moet daaraan een belangrijke bijdrage leveren.

Nederland houdt oog voor gerechtvaardigde belangen van ontwikkelingslanden. Internationale solidariteit en de Millenniumdoelen blijven belangrijk, net als het streven naar een samenhangend beleid.

Om burgers bij ontwikkelingssamenwerking te betrekken, zijn zichtbare resultaten nodig. Ginds en in ons eigen land. Mede daarom streeft het kabinet naar een fundamentele herziening van het ontwikkelingsbeleid, met als leidraad het rapport *Minder pretentie, meer ambitie. Ontwikkelingshulp die verschil maakt* van de Wetenschappelijke Raad voor het Regeringsbeleid.

De 'Basisbrief Ontwikkelingssamenwerking' van november 2010 heeft een eerste aanzet gegeven. De belangrijkste verandering is de verschuiving van sociale naar economische sectoren. De zelfredzaamheid van ontwikkelingslanden krijg meer nadruk; het particuliere initiatief krijgt meer mogelijkheden. Daarnaast wil Nederland een passende rol spelen in de aanpak van wereldwijde problemen als veiligheid, migratie, klimaatverandering, financiële stabiliteit, voedseltekort en watergebrek. Dat vereist positie kiezen, focus aanbrengen. Waar kunnen wij het verschil maken; waar liggen onze belangen?

Naast deze herziening van het ontwikkelingsbeleid spelen ook de in het Regeerakkoord aangekondigde bezuinigingen een rol. Het ODA-budget wordt vanaf 2012 teruggebracht naar het niveau van 0,7% BNP, via een tussenstap van 0,75% BNP in 2011. Dit leidt tot ingrijpende keuzes en bezuinigingen, die samenhangen met de beleidsherziening (zie ook paragraaf II.C en paragraaf V).

Om effectiever en efficiënter te kunnen zijn, moet een kwaliteitsslag worden gemaakt. Kernbegrippen zijn verdere professionalisering van het personeelsbeleid en opbouw van kennis. In het personeelsbeleid komt meer ruimte om versneld en op termijn de deskundigheid op de vier speerpunten te versterken. Dit betekent bijvoorbeeld meer focus op de gerichte instroom van personeel, meer inzet op detacheringen en uitwisselingen met het bedrijfsleven en kennisinstellingen, en verdere flexibilisering van de duur van arbeidscontracten. Ook zullen de relaties met kennisinstellingen, bedrijfsleven en maatschappelijk middenveld onder de loep worden genomen om deze spelers nauwer bij de formulering en uitwerking van nieuw beleid te betrekken. Dit moet niet alleen leiden tot meer en betere resultaten, maar ook tot sterkere banden tussen partijen die betrokken zijn bij ontwikkeling(samenwerking).

Leidraad van deze notitie is het maken van keuzes. Deze keuzes betreffen de speerpunten van beleid en de landen waarmee Nederland een intensieve bilaterale ontwikkelingsrelatie nastreeft. Het doel van deze keuzes is om geconcentreerder, effectiever en professioneler bij te kunnen dragen aan ontwikkeling.

Nederland wil vier speerpunten verder ontwikkelen. Deze speerpunten vormen een goede verbinding tussen de wereldwijde problemen en de Nederlandse kennis: (a) veiligheid en rechtsorde, (b) voedselzekerheid, (c) water en (d) Seksuele en Reproductieve Gezondheid en Rechten (SRGR). Het ministerie van Buitenlandse Zaken zoekt daarbij de samenwerking met andere departementen. Met de keuze voor de productieve sectoren voedselzekerheid en water is expliciet aansluiting gezocht bij de Nederlandse economische topgebieden. Bovendien wordt het aantal partnerlanden drastisch verlaagd. In plaats van 33 landen concentreert de bilaterale ontwikkelingssamenwerking zich voortaan op 15 landen.

Deze brief werkt eerst de vier speerpunten verder uit. Dan volgen uitleg over de landenkeuze en de uiteindelijke landenlijst. Vervolgens wordt beschreven hoe Nederland verantwoord maar onherroepelijk vertrekt uit de afgevallen landen. Tot slot geeft deze brief een schets van de financiële gevolgen. In de Memorie van Toelichting bij de begroting van Buitenlandse Zaken voor 2012 worden de financiële gevolgen in meer detail gepresenteerd.

Een aantal elementen uit de 'Basisbrief Ontwikkelingssamenwerking' zal later dit voorjaar worden uitgewerkt, onder andere multilaterale samenwerking (in breder perspectief) en algemene begrotingssteun. Uitgangspunt voor dit laatste blijft dat begrotingssteun niet wordt gegeven wanneer sprake is van corruptie, schending van mensenrechten of onvoldoende *good governance*. Zoals toegezegd zal het kabinet de Tweede Kamer later dit jaar informeren over transparantie, coherentie en global public goods en, conform het Regeerakkoord, over de discussie over de internationale definitie van uitgaven voor ontwikkelingssamenwerking. De Tweede Kamer ontving al de kabinetsvisie over de toekomst van de Europese OS in de kabinetsreactie op de groenboeken (EU-OS; begrotingssteun) evenals de kabinetsreactie die is opgesteld in het kader van de consultatie 'What funding for EU external action after 2013?'[1]. Meer informatie over individuele exit-strategieën volgt eind 2011, als de plannen door de betrokken posten zijn uitgewerkt.

## II Uitwerking speerpuntenbeleid

### A Inleiding: Uitgangspunten van speerpuntenbeleid

Investeren in duurzame groei stelt ontwikkelingslanden in staat hun problemen zelf op te lossen en minder afhankelijk te worden van hulp. Daarvoor is een sterke private sector in ontwikkelingslanden nodig; het internationaal actieve bedrijfsleven kan behulpzaam zijn. Bij de uitwerking van zijn vier speerpunten bevordert het kabinet daarom een goed ondernemingsklimaat en investeert het in samenwerking met het bedrijfsleven. Dit gebeurt onder meer door schaalvergroting en uitbreiding van publiek-private

[1] Zie Kamerstuk 21 501-04 nr. 121 van 7 februari 2011.

partnerschappen, handhaving en verbetering van het OS-bedrijfsleveninstrumentarium en regelmatig strategisch overleg met het bedrijfsleven.

De uitwerking van de speerpunten kent een aantal uitgangspunten: selectiviteit, samenhang tussen speerpunten, effectiviteit en meerwaarde. De meerjarige landenstrategieën voor de periode 2012-2015 worden onder meer op deze punten beoordeeld.

- **Selectiviteit** Ontwikkelingssamenwerking is gebaat bij scherpe keuzes. Uiteraard spelen veel factoren mee bij het bereiken van onze doelen, maar dat wil niet zeggen dat Nederland op alle terreinen actief moet zijn. Het aantal speerpunten is beperkt tot vier. Milieu, goed bestuur en gender zijn dwarsdoorsnijdende aandachtsgebieden die vooral in dienst van de speerpunten worden ingezet.

- **Samenhang** Synergie draagt bij aan de doeltreffendheid en doelmatigheid. Daarom wordt bij de invulling van de speerpunten aansluiting gezocht bij de Nederlandse prioriteiten van het buitenlandse beleid en de prioriteiten van ontwikkelingslanden. Anders gezegd: hoe kan ontwikkelingssamenwerking bijdragen aan andere doelen?

- **Meerwaarde** De meerwaarde wordt gedefinieerd door de Nederlandse deskundigheid, onze positie ten opzichte van andere donoren en de meerwaarde die een bilaterale samenwerking voor Nederland heeft. Op de speerpunten moet deskundigheid behouden blijven of worden uitgebreid.

- **Effectiviteit** Effecten moeten meetbaar zijn, zonder in cijferfetisjisme te vervallen. Vooraf moet bekend zijn welk resultaat wordt beoogd. De uitgangssituatie moet duidelijk zijn, zodat voortgang kan worden aangetoond. Bovendien moet duidelijk zijn waarom voor een bepaalde interventie wordt gekozen. Plannen worden onderbouwd (*evidence based policy)* met bewijzen of - als dit niet mogelijk is - met veronderstellingen.

Deze principes zullen ook van toepassing zijn op multilaterale en maatschappelijke organisaties. Hieronder is op hoofdlijnen en per speerpunt uitgewerkt wanneer het bilaterale kanaal wordt ingezet, en wat via de multilaterale en particuliere kanalen wordt gedaan. Verder concentreert deze brief zich op het bilaterale kanaal.

## B. Uitwerking speerpunten

### B1 Veiligheid en rechtsorde

Het probleem

De wereldwijde veiligheidsproblematiek is veranderd. Extremistische groeperingen nemen vaker hun toevlucht tot landen en gebiedsdelen met een zwak bestuur en een zwakke rechtsorde (Afghanistan, Pakistan, Jemen, Somalië). Internationale wapen-, drugs- en vrouwenhandelaren bereiken vanuit deze gebieden gemakkelijker het Westen. De illegale handel in grondstoffen (coltan in DRC, papaver in Afghanistan) in landen met zwak bestuur zorgt voor grotere instabiliteit. Conflicten over watervoorraden, de toevoer van olie en gas, en piraterij op aanvoerroutes ondermijnen steeds vaker onze welvaart.

En conflicten tussen en binnen landen leiden tot grotere vluchtelingenstromen en meer illegale immigratie. Veel asielzoekers in Nederland komen uit conflictlanden (Somalië, Afghanistan).

Conflicten zorgen voor veel menselijk leed, belemmeren sociaal-economische ontwikkeling en daarmee ook het bereiken van de Millenniumdoelen.[2] Werkloosheid, uitsluiting, mensenrechtenschendingen of onveiligheid dragen op hun beurt bij aan het ontstaan van gewelddadige conflicten. Die conflicten zijn bovendien desastreus voor de economie. De jaarlijkse kosten van internationale conflictbeheersing worden geschat op $270 miljard per jaar, waarvan 7,2 miljard voor internationale vredesoperaties (VN-operaties; blauwhelmen). Voorkomen is dus niet alleen menselijk, maar ook efficiënt.

Door te werken aan vredesopbouw, conflictpreventie en staatsopbouw streeft de regering ernaar bij te dragen aan het verminderen van tegenstellingen tussen bevolkingsgroepen en het ontstaan van *'ungoverned spaces'* die door terreurgroeperingen en criminele organisaties kunnen worden uitgebuit. Om radicalisering tegen te gaan is het daarbij van belang om de onderliggende oorzaken van uitsluiting, conflicten en instabiliteit in ogenschouw te nemen.

Doelstelling

Nederland zet zich in voor het bevorderen van de menselijke veiligheid (*human security*) in zwakke staten door de onderliggende oorzaken van instabiliteit, conflict en uitsluiting aan te pakken. Dit schept de voorwaarden voor meer veiligheid en ontwikkeling. De problemen vragen om een samenhangende en specifieke benadering op basis van drie doelstellingen:

1. Verbeteren van veiligheid van mensen (*'human security'*) en bevorderen van rechtsorde. Deze aanpakt bevordert de stabiliteit in fragiele staten, die ook van belang is voor de veiligheid van Nederland.
2. Bijdragen aan legitieme overheden met voldoende capaciteit voor uitvoering van de meest wezenlijke functies.
3. Zichtbare resultaten ('vredesdividend') door snelle levering van sociale voorzieningen en werkgelegenheid.

Positie Nederland

Nederland krijgt internationale erkenning voor zijn 3d-samenwerking (*diplomacy, defense and development*) in bijvoorbeeld Afghanistan en Burundi. Naast Buitenlandse Zaken nemen daaraan ook de ministeries van Defensie, V&J en EL&I deel: de *whole of government*-benadering. Uit het Stabiliteitsfonds en het Wederopbouwfonds kan snel ondersteuning op maat worden geboden. Bovendien werkt de Nederlandse overheid samen met onder andere Nederlandse universiteiten, lokale partners, maatschappelijke organisaties en het bedrijfsleven.

Raakvlakken met buitenlands beleid

Het speerpunt 'Veiligheid en rechtsorde in fragiele staten' brengt verschillende delen van het buitenlandse beleid samen in een gezamenlijke benadering. Het speerpunt draagt bij aan de Millenniumdoelen, het mensenrechtenbeleid, het bredere veiligheidsbeleid

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[2] Volgens de OECD/DAC hebben 22 van de 34 armste landen interne conflicten, waardoor de Millenniumdoelen niet worden gehaald en mensen geen bestaan kunnen opbouwen.

(terrorismebestrijding, internationale criminaliteitsbestrijding, vluchtelingenstromen en illegale migratie). Ook economische belangen worden gediend.

Werkwijze
De gezamenlijke benadering betekent een (landen)specifieke combinatie van defensie, diplomatie en ontwikkeling. Bij defensie gaat het bijvoorbeeld om ontwapening en hervorming van de krijgsmacht; bij diplomatie onder meer om ondersteuning van politieke- en vredesprocessen, verzoening en het tegengaan van straffeloosheid; bij ontwikkelingssamenwerking om opbouw van bestuur en rechtsstaat, onder andere door in te zetten op de keten politie-rechtbank-gevangenis, het creëren van werkgelegenheid en levering van basisvoorzieningen.

Nederland zet zich bilateraal in voor zaken die internationaal nog onderbelicht zijn en waarin Nederland relatief goed is, zoals hervorming van de veiligheidssector en ontwikkeling van de rechtsstaat. Ook gaat het om politieke aandacht bij vredesonderhandelingen, en de samenwerking tussen het Nederlandse en lokale bedrijfsleven. Voor het overige heeft multilaterale samenwerking de voorkeur. Internationale vredesmissies, ontwapening, demobilisatieprogramma's en grootschalige investeringen in basisvoorzieningen worden bij voorkeur multilateraal geregeld. Het maatschappelijk middenveld kan bijdragen aan sociale voorzieningen en het gesprek tussen overheid en verschillende bevolkingsgroepen. Het bedrijfsleven speelt vooral een rol in het creëren van werkgelegenheid, en als partner op de speerpunten water en voedselzekerheid.

Doorsnijdende thema's
In zwakke staten is de verbetering van bestuur zo essentieel, dat het een aparte doelstelling vormt. Na conflictsituaties zijn het herstel van vertrouwen in overheidsinstanties (o.a. door corruptiebestrijding) en de opbouw van overheidscapaciteit voor wezenlijke taken als veiligheid, rechtsorde, economische groei en werkgelegenheid van groot belang om de afhankelijkheid van internationale hulp te verminderen en de zelfredzaamheid te bevorderen. Gender krijgt speciale aandacht binnen de drie doelstellingen. Vrouwen worden niet alleen gezien als slachtoffers van conflict, maar ook als belangrijke spelers in wederopbouw en economische ontwikkeling. VN-resolutie 1325 is de leidraad bij concrete activiteiten.[3] Bovendien wordt de synergie tussen de speerpunten versterkt. Bijvoorbeeld tussen water en conflictpreventie in Jemen, en werkgelegenheid en voedselzekerheid in de Palestijnse Gebieden. Ook landgebruik, waterbeheer en grondstoffenexploitatie kunnen leiden tot (internationale) conflicten.

Prioriteiten
1. Inzet op de ontwikkeling van de rechtsstaat door onder meer capaciteitsopbouw, in nauwe samenhang met hervorming van de veiligheidssector en ondersteund door een politieke dialoog.
2. Creëren van werkgelegenheid, als 'vredesdividend' voor de bevolking. Dit is cruciaal voor stabiliteit en een aanknopingspunt voor samenwerking met de private sector.
3. Vergroten van landenspecifieke expertise en het maken van programma's om conflicten te voorkomen door conflictanalyses en samenwerking met lokale spelers (*community-based approach*).

[3] Moties-Ferrier 32 500-V (Nr. 35) en motie-Hachchi 32 500-V (Nr. 38)

4. Inzet op de rol van de vrouw in vredesprocessen[4] met een nieuw Nederlands actieplan voor uitvoering van VN-resolutie 1325 en het MDG3-fonds.
5. Streven naar een effectievere multilaterale inzet in postconflictsituaties.

## B 2. Water

Het probleem
Een groeiend aantal landen heeft te kampen met waterproblemen die voortkomen uit klimaatverandering, overlast, schaarste en vervuiling. Dit heeft gevolgen voor drinkwater, voedselvoorziening, infrastructuur en economische ontwikkeling, maar ook voor (kwetsbare) ecosystemen en de stabiliteit van samenlevingen. Gebrek aan schoon drinkwater en sanitaire voorzieningen veroorzaakt ziekte en (kinder)sterfte, en vergroot de werklast en kwetsbaarheid van meisjes en vrouwen in ontwikkelingslanden[5]. Waterschaarste is een potentiële bron van conflict op lokaal, nationaal en internationaal niveau, terwijl overstromingen vaak resulteren in grote schade en dodelijke slachtoffers. Verzilting in kustgebieden bedreigt de landbouw; de onttrekking van grondwater veroorzaakt bodemdaling, waardoor de kans op overstromingen toeneemt.

Doelstelling
Nederland wil met zijn kennis en ervaring bijdragen aan effectief waterbeheer, met de volgende doelen:
1. Efficiënt en duurzaam watergebruik, vooral in de landbouw (70 procent van het mondiale watergebruik is voor de landbouw).
2. Veilige delta's en beter beheer van stroomgebieden, ook in het kader van klimaatverandering.
3. Verbeterde toegang tot veilig drinkwater en sanitaire voorzieningen.

Positie Nederland
Nederland beschikt over veel (specifieke) kennis en deelt deze ook met andere landen. Vooral onze samenhangende benadering is uniek. Wereldwijd wordt een beroep gedaan op Nederlandse kennis van beheer en inrichting van stroom- en kustgebieden, grensoverschrijdend waterbeheer, duurzame irrigatie- en drainagetechnologie en (afval)waterzuivering. Daarnaast wordt naar Nederland gekeken voor ondersteuning bij aanpassing aan klimaatverandering, het beschermen van stedelijke agglomeraties tegen overstromingen, het ontwikkelen van innovatieve financieringsvormen, en het betrekken van watergebruikers bij planning en uitvoering. Nederland beschikt ook over financiële middelen (bijvoorbeeld voor de inzet van het bedrijfsleven) en kent een sterke samenwerking tussen ministeries. Een goed voorbeeld van die samenwerking is het Water Mondiaal-programma[6]. Het speerpunt water biedt ook kansen voor het Nederlandse bedrijfsleven.

Raakvlakken met buitenlands beleid
Waterbeheer en toegang tot water zijn essentiële elementen van armoedebestrijding, duurzame economische groei en zelfredzaamheid. Vooral productie in relatie tot voedselzekerheid is afhankelijk van goed waterbeheer. Waterverdeling komt in

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[4]Motie-Ferrier 32 500-V (Nr. 34), motie-Hachchi 32 500-V (Nr. 38)
[5] OECD-DAC, januari 2010, "Benefits of investing in water and sanitation: an OECD perspective
[6] Nationaal Waterplan, 2009-2015, hoofdstuk 6: Nederland werkt wereldwijd met water

toenemende mate onder druk te staan in internationale rivierbekkens, en dreigt lokale en internationale spanningen verder te voeden. Nederland draagt al bij aan internationale waterdiplomatie en legt zich daarop nog meer toe. Nederlandse waterdeskundigheid kan ook worden ingezet bij (de preventie van) humanitaire noodsituaties en tijdens wederopbouw. Toegang tot drinkwater en sanitatie is erkend als sociaal-economisch recht[7] en wordt door Nederland actief uitgedragen.

Doorsnijdende thema's

Goed bestuur staat centraal in het waterbeleid. Adequaat waterbeheer en het voorkomen van conflicten die voortkomen uit toegang tot en verdeling van water, vergen sterke instituties met voldoende capaciteit. De verantwoordingsrelatie tussen instellingen en watergebruikers verdient speciale aandacht. In verschillende landen is al ervaring opgebouwd met het verbeteren van inspraak door de gebruikers, het afleggen van rekenschap door de aanbieders van drinkwater, en het vergroten van duurzaamheid en *ownership* van watersystemen. Goed beheer van natuurlijke hulpbronnen is essentieel voor geïntegreerd waterbeheer.

Werkwijze

Nederland werkt bilateraal samen op terreinen waar Nederland een kennisvoorsprong heeft en waar samenwerking tussen overheid, het Nederlandse bedrijfsleven, maatschappelijke organisaties en kennisinstellingen een meerwaarde heeft. Nederland werkt via multilaterale instellingen als UNICEF, de Wereldbank en de Aziatische Ontwikkelingsbank aan de uitvoering van (grootschalige) investeringsprogramma's. Bij deze multilaterale organisaties spant Nederland zich in om de rol van deskundige Nederlandse kennisinstellingen, maatschappelijke organisaties en bedrijven te vergroten.

Prioriteiten

1. Uitbreiding van Publiek-Private Partnerschappen (PPP's) en samenwerkingsprogramma's. Dit kan het snelst binnen de drinkwater- en sanitatiesector, waar al intensief wordt samengewerkt met Nederlandse drinkwaterbedrijven[8], waterschappen, kennisinstellingen, maatschappelijke organisaties en lokale partners.
2. Verbetering van waterbeheer en aanpassing op klimaatveranderingen, gericht op duurzame voedselproductie en veilige delta's. Dit gebeurt met betrokkenheid van het Netherlands Water Partnership (koepelorganisatie van de Nederlandse watersector). Activiteiten op het gebied van drinkwater en sanitatie vormen nu nog het grootste deel van het totale waterprogramma. Activiteiten gericht op vergroting van voedselzekerheid, aanpassing aan klimaatverandering en veilige delta's worden uitgebreid.
3. Het aantal partnerlanden waarin volgens de principes van Water Mondiaal wordt samengewerkt, stijgt met vijf (uitgaande van de landenlijst). Hierbij wordt samenwerking gezocht met betrokken departementen. De keuze van de landen wordt mede gebaseerd op een onderzoek van Netherlands Water Partnership naar de interesse van de Nederlandse watersector in diverse landen.

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[7] Tijdens de 64e AVVN op 28 juli 2010 is het recht op schoon water en sanitatie tot mensenrecht verklaard; tijdens de Human Rights Council 16, maart 2011, is de betreffende resolutie aangenomen.

[8] In Motie Koppejan, 30895 (Nr. 42), werd de regering verzocht om de deskundigheid, kennis en ervaring van Nederlandse drinkwaterbedrijven te benutten ter bevordering van een goede drinkwatervoorziening in ontwikkelingslanden. Drinkwaterbedrijven mogen maximaal 1% van de jaarlijkse omzet inzetten voor ontwikkelingssamenwerking.

## B 3. Voedselzekerheid[9]

Het probleem
Wereldwijd zijn 1 miljard mensen chronisch ondervoed en hebben 2 miljard mensen een tekort aan essentiële voedingsstoffen.[10] Enerzijds staat de productie onder druk door een toenemende strijd om land, water en energie. Anderzijds hebben de allerarmsten te weinig geld om voedsel te kopen. Problemen ontstaan ook als vraag en aanbod niet bij elkaar komen, bijvoorbeeld door falende markten of ontoereikende regelgeving en slechte infrastructuur. Kleine boeren zijn vaak onvoldoende geïntegreerd in de markteconomie. In 2050 moet 70 procent meer voedsel worden geproduceerd en verhandeld. Vooral in Afrika kan de productie nog fors toenemen, zeker gezien de sterk toenemende vraag uit Azië. Maar er zijn veel obstakels te overwinnen. In rurale gebieden, vooral in sub-Sahara Afrika, laat ontwikkeling van de landbouw nog te wensen over. De oorzaken zijn niet alleen landbouwkundig, maar vaak ook politiek of institutioneel. De natuurlijke hulpbronnen voor landbouw en rurale ontwikkeling zijn niet evenredig verdeeld, vaak slecht beheerd en worden schaarser. De private sector kan door marktverstoringen vaak onvoldoende bijdragen aan noodzakelijke productiviteitsstijgingen.

Doelstelling
Het vergroten van voedselzekerheid (Millenniumdoel 1: halvering van honger en het aantal mensen dat onder de armoedegrens leeft) door het stimuleren van duurzame productie, efficiëntere markten, grotere inkomenszekerheid en verbeterde toegang tot gezond voedsel.

Positie Nederland
Nederland heeft veel te bieden, met zijn innovatiekracht en internationaal opererende bedrijven op het gebied van voeding en landbouw, zijn positie als tweede landbouwexporteur ter wereld, zijn toonaangevende kennisinstellingen met expertise over het stimuleren van (rurale) bedrijvigheid en landbouw, zijn ervaring in duurzame handelsketens en de expertise op watergebied. Deze expertise kan worden gecombineerd met de sterke reputatie van Nederland als donorland. De Nederlandse programma's ter ondersteuning van bedrijvigheid en ondernemingsklimaat (PUM, PSI, ORIO, IDH en CBI[11]) zijn inzetbaar voor voedselzekerheid. Het samenbrengen van kennis en instrumenten kan het speerpunt bovendien een extra impuls geven. Buitenlandse Zaken en EL&I ontwikkelen een pilotprogramma op het gebied van voedselzekerheid.

Raakvlakken met buitenlands beleid
Voedselzekerheid sluit aan bij Nederlandse kennis en kunde. Daardoor ontstaan investerings- en handelsmogelijkheden voor Nederlandse bedrijven en instellingen. Economische groei en voedselzekerheid leveren ook een bijdrage aan vrede en veiligheid,

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[9] Definitie van World Food Summit : 'Food and nutrition security exists when all people, at all times, have physical, social and economic access to sufficient food which meets their dietary needs and food preferences for an active and healthy life.'

[10] The State of Food Insecurity in the World (FAO 2010)
[11] Programma Uitzending Managers (PUM), Private Sector Investeringsprogramma (PSI), Ontwikkelingsrelevante Infrastructuurontwikkeling (ORIO), Initiatief Duurzame Handel (IDH), Centrum ter Bevordering van de Import in ontwikkelingslanden (CBI).

omdat conflicten mede ontstaan door uitsluiting en armoede. Hoge voedselprijzen kunnen tot ontwrichting leiden. Beter gebruik van water in de landbouw kan leiden tot een vermindering van conflicten over water. Meer zeggenschap van vrouwen over voedsel leidt tot kinderen met een hoger geboortegewicht, minder moedersterfte en beter gevoede kinderen. De voeding in de eerste levensjaren is erg bepalend voor de ontwikkeling van kinderen.

Werkwijze

Het bevorderen van voedselzekerheid betekent een hogere en duurzamere productie, efficiënte verkoop en ruimere toegang tot goed voedsel. Nederland zal markten en bedrijven vooruit helpen. Waar mogelijk worden Publiek-Private Partnerschappen ontwikkeld. Dit alles gebeurt in de eerste plaats via het bilaterale kanaal en met het inschakelen van de private sector. Aandachtsgebieden zijn landrechten, financiële dienstverlening op het platteland, versterken van producentenorganisaties, (agrarisch) beroepsonderwijs, integratie van kleine boeren in marktketens en rurale infrastructuur. Multilaterale samenwerking met bijvoorbeeld IFAD en IFC draagt bij aan schaalvergroting en harmonisatie.

Doorsnijdende thema's

Goed bestuur is van groot belang voor voedselzekerheid, economische groei en private-sectorontwikkeling. Een goed functionerende rechtsstaat is essentieel voor een gunstig ondernemingsklimaat. Rechtszekerheid is niet alleen een voorwaarde voor het lokale, maar ook voor het Nederlandse bedrijfsleven. Landrechten, ook voor vrouwen, zijn fundamenteel. Vrouwen spelen een belangrijke rol in voedselproductie en -verkoop, maar hebben vaak minder toegang tot productiemiddelen als kapitaal, kennis en land. Ook in de landbouw is speciale aandacht voor gender daarom belangrijk. Duurzaam beheer van natuurlijke hulpbronnen draagt mede bij aan de beschikbaarheid van water en voorkomt erosie.

Prioriteiten

1. Een duurzame productiviteitsverhoging en duurzaam land- en watergebruik door het stimuleren van innovatie in samenwerking met kennisinstellingen.
2. Duurzame ketenontwikkeling, zodat lokale producenten ook kunnen profiteren van internationale en regionale handel. Het Initiatief Duurzame Handel en andere publiek-private samenwerkingen spelen hierin een belangrijke rol.
3. Betere toegang tot goede voeding voor armere bevolkingsgroepen door hogere werkgelegenheid, sociale voorzieningen en het verhogen van de duurzame productie van voedsel.
4. Creëren van gunstige omstandigheden voor producenten door het wegnemen van knelpunten, betere landelijke infrastructuur, steun aan boerenorganisaties en financiële dienstverlening (inclusief verzekeringen).
5. Stimuleren van lokale en regionale markten, en het bevorderen van internationale markttoegang en –handel. Dit zorgt voor koppeling van consumenten en producenten. Bovendien kunnen marktprikkels dienen als leidraad voor economische ontwikkeling.

## B 4. Seksuele en Reproductieve Gezondheid en Rechten (SRGR)

Het probleem

Zwanger worden, zwanger zijn en bevallen, gaan in ontwikkelingslanden vaak gepaard met ziekte en complicaties. Het is veelzeggend dat van alle Millenniumdoelen de minste winst is geboekt op het terrein van moedersterfte en het verbeteren van de 'reproductieve gezondheid'. Dit is het gevolg van zwakke gezondheidszorg, genderongelijkheid (in toegang tot onderwijs[12] en voedsel, maar ook in zelfbeschikkingsrecht), ziektes als malaria en HIV/AIDS, het gebrek aan anticonceptie en beperkte mogelijkheden tot veilige abortus. Moedersterfte ontwricht gezinnen, maar belemmert ook economische groei[13]. Gebrekkige seksuele en reproductieve gezondheid en rechten[14] zorgen voor een hoge en onevenwichtige bevolkingsgroei. Dat heeft gevolgen voor voedselzekerheid, werkgelegenheid en de beschikbaarheid van schaarse hulpbronnen en basisvoorzieningen.

Doelstelling

Nederland zet zich in voor het verminderen van moedersterfte en het verzekeren van algemene toegang tot 'reproductieve gezondheid' (Millenniumdoel 5). Specifieke doelen zijn:

1. Verbeterde toegang tot kwalitatief goede anticonceptie, medicijnen, vaccins en middelen voor 'reproductieve gezondheid'.
2. Voorlichting van jongeren over seksualiteit, zodat ze zelf keuzes kunnen maken in relaties, seks en het gebruik van anticonceptie.
3. Verbetering van de kwaliteit van en de toegang tot publieke en private gezondheidsdiensten, in relatie tot SRGR.
4. Wegnemen van belemmeringen bij toegang tot gezondheidszorg voor gemarginaliseerde groepen zoals drugsgebruikers, prostituees, homo's en gevangenen in diverse landen.[15]

Positie Nederland

Hoewel veel (donor)organisaties actief zijn op dit terrein, is vooral Nederland een vooruitstrevende en standvastige pleitbezorger van 'seksuele en reproductieve gezondheid en rechten'. Ondanks dat dit voor velen een controversieel onderwerp is. Nederland heeft in eigen land ervaring opgedaan met jongeren en seksualiteit, toegang tot anticonceptie, voorkomen van onveilige abortus, 'reproductieve rechten' in het algemeen en de rechten van lesbiennes, homo's, biseksuelen, transseksuelen, prostituees en drugsgebruikers in het bijzonder. De Nederlandse ervaring met publiek-private samenwerking in de gezondheidzorg, bijvoorbeeld met ziektekostenverzekeringen, is nuttig voor ontwikkelingslanden die samen met private partijen ('reproductieve') gezondheidszorg op lange termijn willen financieren (met de

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[12] Meisjesonderwijs zorgt er onder andere voor dat vrouwen op latere leeftijd zwanger worden, vermindert kans op HIV infecties en verlaagt het totaal aantal kinderen dat een vrouw krijgt.

[13] Het productiviteitsverlies door de sterfte van vrouwen tijdens de zwangerschap en bevalling kost wereldwijd $15 miljard per jaar, Women Deliver 2010

[14] SRGR betreft een breed scala aan onderwerpen zoals toegang tot prenatale en postnatale zorg, veilige bevallingen, family planning, het voorkomen en behandelen van seksueel overdraagbare aandoeningen (inclusief HIV/AIDS), seksuele voorlichting, veilige abortus, vrouwenbesnijdenis en moeder- en zuigelingensterfte.

[15] Zie motie-Hachchi, 32 500-V (Nr 37)

keuze van SRGR als speerpunt wordt ook aangesloten bij een van de economische topgebieden: *life sciences*).

Raakvlakken met buitenlands beleid
SRGR draagt bij aan verschillende doelstellingen van het buitenlandse beleid, om te beginnen het bevorderen van mensenrechten. Moedersterfte schendt het recht op leven; deze schending is vaak te vermijden. 'Reproductieve rechten' dragen bij aan het bestrijden van genderongelijkheid. SRGR helpt bij het afremmen van de bevolkingsgroei. Gezondheid van vrouwen en jonge kinderen beïnvloedt ook de voedselzekerheid en daarmee de economische groei. Andersom geldt dat een vrouw die chronisch ondervoed is, grote kans heeft op een kind met te laag geboortegewicht. Zo wordt ondervoeding van generatie op generatie overgedragen. Dat gaat gepaard met een grotere kans op chronische ziekten en hogere zorgkosten.

Werkwijze
Nederland werkt nauw samen met de VN-instellingen. Dat zijn vooral UNFPA (die het mandaat heeft voor SRGR), WHO (essentiële partner voor de ontwikkeling van standaarden en het verbeteren van de gezondheidszorg) en het SRGR-onderzoeksprogramma van de VN. Multidonorfondsen dienen voor schaalvergroting. Voorbeelden van dergelijke fondsen zijn het Global Programme for Reproductive Health Supplies, de Global Alliance for Vaccine and Immunisations (GAVI) en het Global Fund to fight Aids, Tuberculose and Malaria (GFATM)[16]. Nederland werkt samen met het bedrijfsleven en maatschappelijke organisaties uit binnen- en buitenland om de toegang tot anticonceptie en andere voorzieningen te vergroten. De farmaceutische industrie is ook betrokken, bijvoorbeeld in Product Development Partnerships voor het ontwikkelen van nieuwe vaccins, voorbehoedmiddelen en medicijnen.

Doorsnijdende thema's
Gendergelijkheid en SRGR liggen in elkaars verlengde, zoals eerder opgemerkt. Het gaat bij het bestrijden van moedersterfte ten diepste om het recht op leven. Goed bestuur is een belangrijke voorwaarde voor dienstverlening aan de bevolking en verdient de nodige aandacht. Gezondheids- en SRGR-diensten laten door mismanagement nog vaak te wensen over. Corruptie kan er bijvoorbeeld toe leiden dat er moet worden betaald voor SRGR-diensten die eigenlijk gratis zijn en dat (zwangere) vrouwen daarom niet de juiste zorg krijgen.

Prioriteiten
1. Pleitbezorging en beïnvloeding van beleid, op internationaal en nationaal niveau.
2. Effectieve dienstverlening door betere aansluiting tussen overheid en private sector.
3. Capaciteitsversterking in de gezondheidszorg voor betere dienstverlening voor SRGR.
4. Gericht onderzoek om toegang tot voorzieningen te verbeteren, bijvoorbeeld met Product Development Partnerships.
5. Onderwijs, onder andere door training van personeel en het beïnvloeden van lesprogramma's.

[16] Zie amendement Dijkhoff-Irrgang 32 500-V (Nr.22) en amendement Ferrier-Dijkhoff 32 500-V (Nr. 55).

## C Bezuinigingen

Geen prioriteiten zonder posterioriteiten. De 'Basisbrief' noemt onderwijs en gezondheidszorg. Niet omdat deze thema's onbelangrijk zijn, maar omdat de Nederlandse meerwaarde op deze terreinen in vergelijking met andere donorlanden relatief beperkt is. Zij verdwijnen niet uit het Nederlandse beleid, maar ondersteunen voortaan de vier speerpunten. Dat betekent bijvoorbeeld dat de inzet op het beroepsonderwijs en onderwijs in zwakke staten wordt voortgezet of zelfs vergroot[17], of dat beroepsonderwijs in relatie tot voedselzekerheid of watermanagement extra aandacht kan krijgen. Minder geld gaat onder andere naar:

- Bilaterale inspanningen op basisonderwijs die niet bijdragen aan de vier speerpunten.
- De bijdrage aan het Fast Track Initiative.
- Sectorale begrotingssteun aan de onderwijssector.
- Centrale onderzoeksprogramma's, voor zover deze los staan van de speerpunten.

Voor gezondheidszorg geldt globaal hetzelfde. Investeringen in gezondheidszorg zijn niet langer een doel op zich, maar moeten bijdragen aan SRGR. Dit leidt tot bezuinigingen op de volgende terreinen:

- Wereldwijde fondsen voor ziektebestrijding.
- Nederlandse bijdragen aan internationale initiatieven gericht op brede gezondheidssystemen.
- Bilaterale inzet op HIV/AIDS.

Gezien het Regeerakkoord zijn ook bezuinigingen op thema's als goed bestuur en milieu onontkoombaar. Minder geld gaat vooral naar de onderdelen van deze thema's die de speerpunten niet ondersteunen. Activiteiten en programma's die de speerpunten wel ondersteunen, worden zo veel mogelijk ontzien.

Omdat 'goed bestuur' een instrumenteel onderwerp is voor de speerpunten, zal minder worden besteed aan programma's die de speerpunten niet ondersteunen:

- Zelfstandige bilaterale programma's voor goed bestuur, zoals medialiberalisering en *civic education*. Programma's voor corruptiebestrijding blijven bestaan, omdat zij onder meer bijdragen aan stabiliteit, transparantie en een goede besteding van publieke gelden, waaronder ontwikkelingsgelden.
- Centraal gefinancierde programma's van multilaterale organisaties, zoals de Governance Partnership Facility van de Wereldbank.

De onderdelen van het milieubeleid voor zover ze de vier speerpunten niet ondersteunen, krijgen minder geld. Deze zijn grofweg:

- Bossenprogramma's. Uitzonderingen zijn duurzame productie en samenwerking met het bedrijfsleven op het gebied van hout. Het gaat hier niet om bosbeleid of bosbeheer, maar om het verduurzamen van de productieketen. Dit draagt direct bij aan economische ontwikkeling.

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[17] Motie-Van der Staaij, 32 500-V (Nr. 49)

- Programma's voor hernieuwbare energie in ontwikkelingslanden, na beëindiging van de nog lopende programma's die door het vorige kabinet zijn geïnitieerd.
- Inzet op biodiversiteit, behalve in relatie tot waterbeheer en voedselzekerheid.
- Generieke ondersteuning van nationale milieuplannen.

## III Landenkeuze

### A Uitgangspunten

De 33 landen waarmee Nederland een bilaterale ontwikkelingsrelatie onderhoudt, zijn als uitgangspunt genomen voor de landenkeuze. De volgende gegevens zijn betrokken in het selectieproces:

- Er moet voldoende perspectief zijn op het behalen van ontwikkelingsresultaten, mede door de Nederlandse meerwaarde, en het dienen van de Nederlandse belangen. De mogelijkheden voor Nederland om in te zetten op de vier speerpunten en de bredere Nederlandse belangen hebben daarom een belangrijke rol gespeeld in het selectieproces.

- Het inkomens- en armoedeniveau. Welke landen hebben een laag inkomensniveau en welke landen hebben inmiddels de status van middeninkomenland bereikt? Welke behoeften hebben landen? Van belang is ook in hoeverre landen door belastingheffing kunnen voorzien in hun eigen inkomsten. Ten slotte is ook het aandeel van ontwikkelingsgeld in de overheidsbegroting vastgesteld.

- Er is een inventarisatie gemaakt van de mogelijkheden om de speerpunten van het kabinet en de vier speerpunten van de 'Basisbrief' vorm te geven. Daartoe is voor elk van de 33 huidige partnerlanden een 'quick scan' gemaakt, om te bezien waar kansen liggen en waar Nederland iets te bieden heeft. Er is gekeken naar specifieke problemen, trends en belemmeringen op elk van de speerpunten. Ook is inzichtelijk gemaakt welk belang lokale spelers als overheid, private sector en maatschappelijk middenveld hechten aan deze belemmeringen en in welke mate samenwerking met Nederland een meerwaarde heeft (ten opzichte van andere donoren). Ten slotte is bezien of er ook een breder Nederlands belang bestaat en of synergie tussen de verschillende speerpunten mogelijk is.

- Kansen voor en belangen van de meest betrokken vakdepartementen, met als centrale vragen: in welke landen kan Nederland met kennis, expertise en netwerken bijdragen aan zelfredzaamheid? En in welke landen spelen specifieke Nederlandse belangen op terreinen als veiligheid en economie?

- Omvang van het lopende hulpprogramma in financiële termen, het aantal Nederlandse ontwikkelingsactiviteiten en de meerwaarde van Nederland als donor. Uitfasering ligt meer voor de hand in landen waar afbouw van een programma sneller kan en in goede samenwerking met het ontwikkelingslanden.

- De mate van goed bestuur, inclusief democratisering, naleving van mensenrechten en corruptiebestrijding (dan wel mogelijkheden om deze te bevorderen).

- De mate waarin eventuele sluiting of omvorming van het ontwikkelingsprogramma bijdraagt aan de voorgenomen bezuinigingen op het postennet. Hierover ontvangt u nadere informatie bij de beantwoording van de motie-Nicolaï.

Om de effectiviteit te vergroten (Verklaringen van Parijs en Accra), zorgvuldig donorschap te stimuleren en *donor orphans* te vermijden, is bij de landenkeuze extra aandacht gegeven aan de werkverdeling tussen donoren. Met de beperking van (speerpunten en) partnerlanden wil Nederland de onderlinge werkverdeling verbeteren. Waar mogelijk is de Nederlandse keuze van partnerlanden afgestemd met gelijkgezinde donorlanden en de EU.

Om hiertoe verdergaande afspraken te maken, organiseerde de staatssecretaris voor Ontwikkelingssamenwerking in de marge van de Informele OS-Raad een informeel overleg over werkverdeling met zes andere gelijkgestemde lidstaten: het Verenigd Koninkrijk, Duitsland, Denemarken, Zweden, België en Spanje. Het verslag aan de Tweede Kamer zegt hierover: 'Het belang van het Nederlandse initiatief om beter af te stemmen nu veel donoren hun bilaterale ontwikkelingsbeleid herzien, werd breed gedeeld. Er werd eveneens geconstateerd dat landenkeuzes vaak sterk nationaal gedreven processen zijn. Dan valt de coördinatieslag gemakkelijk weg. De aanwezigen zegden toe elkaar goed op de hoogte te houden van de veranderingen in sectorkeuze en landenconcentratie en waar mogelijk met concrete oplossingen te helpen bij knelpunten die kunnen ontstaan door terugtrekking uit een sector of een land. Er was duidelijk politiek committent om nu verder werk te maken van de werkverdelingsagenda, waarbij pragmatische samenwerking centraal zou moeten staan. Grootschalige en ambitieuze afspraken over werkverdeling zijn voorlopig niet aan de orde. En marge van de voorjaarsvergadering van Wereldbank zal opnieuw hierover gesproken worden.' Eurocommissaris Andris Piebalgs is vooraf en achteraf over dit initiatief geïnformeerd. De Europese Commissie ziet deze *pilot* als een steun voor haar coördinerende rol.

**B Meer focus op minder landen**

De uitkomst van het selectieproces is een lijst van landen die in aanmerking komen voor de status van partnerland. Partnerlanden zijn landen waarmee Nederland een meerjarige bilaterale ontwikkelingsrelatie onderhoudt en waar aan de post gedelegeerde financiële middelen worden ingezet. In partnerlanden worden programma's voor de speerpunten water, SRGR, voedselzekerheid en veiligheid en rechtsorde uitgevoerd. De inzet van mensen en middelen wordt afgestemd op deze speerpunten. Bij de inzet op de vier speerpunten in het partnerland worden gender, goed bestuur en milieuaspecten volledig en landenspecifiek meegenomen. De regering hanteert voor de bilaterale programma's in partnerlanden een financiële ondergrens van (vooralsnog) 15 miljoen euro.
De vorige regering heeft de partnerlanden in drie profielen verdeeld. Per profiel gelden specifieke doelen. De regering handhaaft deze indeling omdat hieruit de keuze en vormgeving van de programma's logisch kan worden afgeleid. Het is goed mogelijk dat de middelen voor profiel II (vooral rechtsstaatontwikkeling en conflictpreventie) deels ook in andere profielen worden ingezet.

Landen in profiel 1 zijn lage-inkomenslanden waar hulp een belangrijke rol in ontwikkeling speelt. Deze landen beschikken over onvoldoende middelen om de investeringen te doen die nodig zijn om de Millenniumdoelen te halen. In de landen van

profiel 2 (fragiele staten) vormt een gebundelde benadering van vrede, veiligheid en ontwikkeling (inclusief rechtsstaatontwikkeling) de kern van het programma. Het gaat om een gelijktijdige inzet op veiligheid, legitiem bestuur en sociaal-economische ontwikkeling. In profiel 3 zitten landen met een gezonde economische groei. Bij profiel 3 landen is sprake van inzet op de vier prioritaire speerpunten. In de komende jaren zal het ODA-budget voor deze groep landen echter afnemen, in de verwachting dat betrokken landen steeds meer in staat zullen zijn hun eigen ontwikkeling vorm te geven zonder bilaterale ODA-inspanningen.

Voor een aantal voormalige partnerlanden uit profiel 3 wordt een nieuw instrument gecreëerd: de in de 'Basisbrief Ontwikkelingssamenwerking' aangekondigde transitiefaciliteit. Deze faciliteit is een landenspecifiek instrument voor (bijna-) middeninkomenlanden om de overgang van een bilaterale ontwikkelingsrelatie naar een wederzijds profijtelijke economische samenwerking mogelijk te maken. Deze faciliteit is ook gericht op het verder verbeteren van het ondernemingsklimaat in sectoren met kansen voor Nederlandse bedrijven. De inzet van Nederlandse kennis en kunde wordt via de transitiefaciliteit bevorderd.

Met de transitiefaciliteit worden bestaande instrumenten onder één paraplu gebracht met landenspecifieke interventies die bijdragen aan de overgang van ontwikkelingssamenwerking naar economische samenwerking. Denk aan het inkopen van kennis, het vormgeven van de 'makelaarsrol' die de ambassade wil spelen om partijen bij elkaar te brengen, gerichte financiële ondersteuning, technische assistentie, communicatie, studie- en opleidingsmogelijkheden, en bezoekersprogramma's. Ambassades in de betrokken landen worden uitgenodigd met voorstellen te komen. Andere departementen, in het bijzonder EL&I en I&M, zijn nauw betrokken bij opstelling en implementatie. In tegenstelling tot bij profiel 3 landen is de inzet niet beperkt tot de vier prioritaire speerpunten. Uit de transitiefaciliteit kunnen activiteiten worden ondersteund die bijdragen aan economische samenwerking in brede zin.

In lijn met de 'Basisbrief' hanteert het kabinet een lijst van 15 partnerlanden.[18] De geselecteerde landen scoren hoog op de uitgangspunten voor de landenkeuze (zie IIIA). In het uiteindelijke selectieproces zijn alle genoemde criteria betrokken en meegewogen. De ambassades in de partnerlanden, evenals de vakdepartementen, zijn nauw betrokken geweest bij het besluitvormingsproces. Uiteindelijk heeft dit geleid tot de keuze voor de volgende 15 partnerlanden:

| Profiel I | Profiel II | Profiel III |
|---|---|---|
| 1. Benin | 7. Afghanistan | 12. Bangladesh |
| 2. Ethiopië | 8. Burundi | 13. Ghana |
| 3. Mali | 9. Jemen | 14. Indonesië |
| 4. Mozambique | 10. Palestijnse gebieden | 15. Kenia |
| 5. Oeganda | 11. Soedan | |
| 6. Rwanda | | |

[18] Zie bijlage voor een nadere toelichting

De landen die hier niet zijn genoemd, hebben niet langer de status van partnerland[19]. Uitfasering van de hulp in deze landen gebeurt zorgvuldig (zie paragraaf IV).

**Transitiefaciliteit** Colombia, Vietnam en Zuid-Afrika komen in aanmerking voor de transitiefaciliteit.

**Noord-Afrika & Midden-Oosten** Het kabinet volgt de ontwikkelingen in Noord Afrika en het Midden-Oosten nauwgezet. De Europese Unie zal daar een grote rol spelen. Nederland zal nauw samenwerken met EU-lidstaten, maar ook de bilaterale relatie met Egypte tegen het licht houden. Het kabinet zal bezien welke rol ontwikkelingssamenwerking kan spelen voor het transitieproces in deze regio in het algemeen en Egypte in het bijzonder. Net als destijds in Oost-Europa is aan te nemen dat hier programma's worden ontwikkeld die veel breder zijn dan het raamwerk van ontwikkelingssamenwerking. Het kabinet komt daarop terug.

**Voormalige koloniën** Suriname is geen partnerland meer, maar blijft nauw met Nederland verbonden door de gedeelde geschiedenis, gemeenschappelijke taal en sociaal-economische netwerken. In oktober 2008 besloten Nederland en Suriname gezamenlijk over de besteding van de laatste nog resterende verdragsmiddelen. Zoals toegezegd tijdens de begrotingsbehandeling in december 2010, ontvangt de Tweede Kamer dit voorjaar een notitie over de nieuwe invulling van de betrekkingen met Suriname. Ook met Indonesië heeft Nederland een bijzondere band. Dat Indonesië wel een partnerland blijft, vloeit vooral voort uit het inkomensniveau. De grote maatschappelijke betrokkenheid bij de ontwikkelingen in Indonesië rechtvaardigen een verdere verdieping en verbreding van de relatie. Het ontwikkelingsprogramma sluit hierbij aan. Maar nu Indonesië zich verder ontwikkelt, blijft het zaak om de relatie ook buiten de ontwikkelingskaders op passende wijze vorm te geven.

**Pakistan** Pakistan is niet langer partnerland. Nederland heeft daar als donor weinig toegevoegde waarde. Onze bijdrage is in vergelijking met enkele grote donorlanden bescheiden. Maar de sociaal-economische en politieke ontwikkelingen in Pakistan blijven zorgelijk en hebben een destabiliserend effect op de situatie in Afghanistan, waar Nederland de komende jaren met een politietrainingsmissie actief is. Voor activiteiten op het gebied van vrede, veiligheid en stabiliteit blijft het kabinet aanzienlijke fondsen beschikbaar stellen.

**Guatamala & Nicaragua** De bilaterale ontwikkelingsrelatie met Guatemala en Nicaragua wordt weliswaar afgebouwd, maar Nederland trekt zich niet volledig terug uit beide landen. De mensenrechtensituatie, politieke ontwikkelingen en de gevolgen van grensoverschrijdende criminaliteit in Centraal-Amerika baren Nederland zorgen. Nederland heeft baat bij stabiliteit in de regio, mede vanwege de nabijheid van de Caribische landen van het Koninkrijk. Analoog aan de Britse benadering begint het kabinet een regionaal programma, gericht op de verbetering van de mensenrechtensituatie, het democratiseringsproces en de veiligheidssituatie in Centraal-Amerika.

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[19] Bolivia, Burkina Faso, DRC, Egypte, Georgië, Guatemala, Kosovo, Moldavië, Mongolië, Nicaragua, Pakistan, Senegal, Suriname, Tanzania, Zambia

### C Centrale fondsen

Inperking van het aantal partnerlanden betekent niet dat in andere landen geen Nederlands ontwikkelingsgeld meer wordt geïnvesteerd.
Ten eerste blijven de multilaterale fondsen bestaan. De Nederlandse bijdragen aan multilaterale instellingen weerspiegelen uiteraard de Nederlandse speerpunten, maar deze instellingen zijn en blijven vrij in hun eigen landenkeuze.
Ten tweede is er nog het maatschappelijke kanaal. In het kader van MFS II is met de maatschappelijke organisaties afgesproken dat zij minimaal 60 procent van hun inspanningen moeten richten op de huidige partnerlanden (33). Het kabinet vindt dat ook een goede zaak: de toegevoegde waarde van maatschappelijke organisaties en multilaterale instellingen schuilt vooral in hun netwerken, expertise en allianties.
Ten derde zijn er landen die geld ontvangen uit centrale programma's en fondsen van Buitenlandse Zaken. Ook staat noodhulp per definitie ter beschikking aan alle arme landen. Bovendien heeft het OS-bedrijfsleveninstrumentarium, in overeenstemming met de wensen van het Nederlands bedrijfsleven, een reikwijdte groter dan 50 landen. De toegankelijkheid van dit intrumentarium wordt vergroot, onder meer door eenvoudiger regelgeving. Het Stabiliteitsfonds staat open voor alle DAC-landen. Tot slot is ook een beroep op het Fonds voor Migratie en Ontwikkeling[20], en het Mensenrechtenfonds mogelijk.

## IV Uitfasering: onomkeerbaar, maar verantwoord.

De vermindering van het aantal partnerlanden en de keuze voor vier speerpunten maken uitfaserings- of transformatiestrategieën noodzakelijk. Nederland wil een betrouwbare partner zijn. Lopende afspraken en toezeggingen worden zoveel mogelijk gerespecteerd. Maar in uitzonderlijke gevallen moeten bestaande afspraken met bilaterale, multilaterale en maatschappelijke partijen worden aangepast.
De uitfasering of transformatie van de ontwikkelingssamenwerkingsrelatie wordt goed voorbereid en gepland, langs de lijnen van de beleidsbrief van 2009[21]. Hoewel de vermindering van het aantal partnerlanden een Nederlandse keuze is, streeft het kabinet - in overeenstemming met de Verklaring van Parijs en de Accra Agenda for Action - naar een gezamenlijke aanpak (*mutual accountability*).

De volgende aspecten zijn van belang:

- Tijdige communicatie over de besluitvorming.
- Een planning die betrokkenheid van het ontvangende land mogelijk maakt.
- Het nakomen van juridische verplichtingen en zoveel mogelijk rekening houden met gedane toezeggingen.

Ook is het van belang rekening te houden met de institutionele capaciteit van het partnerland, zodat de regering in staat wordt gesteld om gaten op te vullen. Dit om kapitaalvernietiging te vermijden en geboekte resultaten blijvend te maken. Bij de afbouw en sluiting van programma's, en vaststelling van budgetten zorgt het kabinet daarom voor voldoende flexibiliteit. Nederland bespreekt zorgvuldig met andere donoren in hoeverre de door Nederland gesteunde activiteiten overdraagbaar zijn. Zowel in gevallen waar het hele programma stopt als in gevallen waar één sector wordt gesloten,

[20] De Tweede Kamer zal binnenkort separaat een brief ontvangen over Migratie & Ontwikkelingssamenwerking.
[21] Tweede Kamer, vergaderjaar 2008-2009, 31250, nr. 56

geldt een inspanningsverplichting om adequate vervangende donoren te vinden. Dat kan bijvoorbeeld door een 'uitruil' met andere donorlanden. Nederland voert hierover al overleg met gelijkgestemde landen. Die landen zijn: Duitsland, het Verenigd Koninkrijk, Zweden, Denemarken, Spanje en België. Uiteraard wordt eerst bezien of landen voortaan zelf in staat zijn programma's te financieren.

Deze punten vormen geen blauwdruk voor het succesvol beëindigen of veranderen van de hulprelatie. Maatwerk staat centraal en de verschillende punten kunnen in de ene situatie belangrijker zijn dan in de andere.

Maatwerk krijgt vorm in een door de post uitgewerkte exit- of transformatiestrategie. Deze strategie komt in plaats van de Meerjaren Strategische Plannen (MJSP's) voor 2012-2015 en wordt verwerkt in de begrotingscyclus.

Over de voortgang van de uitfasering zal de regering de Tweede Kamer via de begroting voor ontwikkelingssamenwerking en de verantwoording daarvan jaarlijks informeren, te beginnen met de verantwoording over 2011.

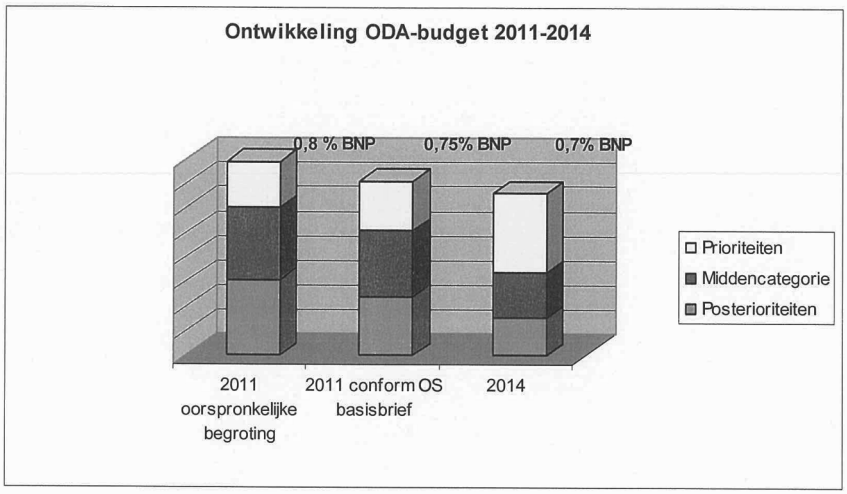
## V Financiële contouren

Het Regeerakkoord leidt tot een verlaging van de uitgaven naar het niveau van 0,7 procent van het BNP vanaf 2012. Samen met enkele aanvullende maatregelen leidt dit tot de volgende bezuinigingsopgave in de huidige kabinetsperiode.

| Maatregelen Regeerakkoord | 2011 | 2012 | 2013 | 2014 |
|---|---|---|---|---|
| (EUR mln) | | | | |
| Aanpassing ODA-budget | 290 | 640 | 660 | 690 |
| Klimaatmiddelen boven 0,8% BNP | 50 | 200 | | |
| Hogere toerekeningen | 60 | 60 | 60 | 60 |
| Totaal | 400 | 900 | 720 | 750 |

In de 'Basisbrief' en de Incidentele Suppletoire Begroting (inclusief de aangenomen amendementen) is het budgettaire beeld voor 2011 ingevuld. Aan de orde zijn nu de verschuivingen en bezuinigingen voor de periode 2012-2014.

In deze brief worden de thematische contouren geschetst van de begroting richting 2014, het laatste kabinetsjaar. Zo worden de doelen van het kabinet zichtbaar, zowel voor de bezuinigingen als voor de vier speerpunten. Uit onderstaand diagram blijkt een ambitieuze tweeledige doelstelling. Ten eerste de budgettaire opgave zoals verwoord in het Regeerakkoord: de aanpassing van het ODA-budget, via een tussenstap van 0,75% BNP in 2011, naar een niveau van 0,7% BNP vanaf 2012. Ten tweede het streven om binnen de kaders van dit krimpend budget tot een aangepaste themavoering te komen.




Zoals ook in de Basisbrief aangegeven is het streven om tot een hogere financiële inzet ten aanzien van de vier speerpunten (veiligheid en rechtsorde, water, voedselzekerheid en tot slot SRGR/moedersterfte) te komen. Daarnaast is ook sprake van een hogere inzet ten aanzien van private sector ontwikkeling. Dit weerspiegelt eveneens de verschuiving van sociale naar economische sectoren. De doelstelling is bijna een verdubbeling van het aandeel van deze speerpunten in het ODA-budget in 2014 ten opzichte van de situatie in 2011. Deze versterkte inzet gaat via het bilaterale, het maatschappelijke, het multilaterale en het bedrijfslevenkanaal. Zie in dit verband ook Hoofdstuk II-B.

De stijging bij de speerpunten heeft een daling tot gevolg van het aandeel van de middencategorie en de posterioriteiten. Bij de middencategorie gaat het om budgetten waarbij, in het verlengde van de Basisbrief, vanuit beleidsmatige overwegingen besloten is om beperkte bezuinigingen door te voeren. Dit betreft onder meer noodhulp, gender, milieu, goed bestuur en de bijdragen aan de regionale ontwikkelingsbanken. De relatief grootste bezuinigingen betreffen de laatste categorie. Het gaat hierbij om de budgetten voor onderwijs, gezondheidszorg, HIV/AIDS en het maatschappelijk middenveld. Uitzondering hierop is het budget voor MFS-II waarover besloten is om in de jaren 2012-2015 niet aanvullend te bezuinigen. Zie ook hoofdstuk II-C voor een nadere invulling van de bezuinigingen.[22]

De specifieke (programmatische) invulling is een meerjarig proces dat tijdens deze kabinetsperiode nader wordt vormgegeven. De Tweede Kamer zal hierover in detail worden geïnformeerd met de geëigende begrotingsstukken van de bij ODA betrokken departementen (Begroting 2012 en verder).

[22] In het verlengde van de Basisbrief zijn in dit overzicht niet de uitgaven meegenomen waarbij geen kortingen mogelijk zijn (toerekeningen EU en asiel, schuldverlichting (EKI), de apparaatskosten en de verplichte bijdragen aan internationale instellingen en het Europees Ontwikkelingsfonds). Ook is weer WB/IDA niet meegenomen.

**Bijlage**

**Onderbouwing keuze per partnerland**

**Profiel 1**

**Benin**
Laag inkomen ($ 750); mogelijkheden voor thema's water, voedselzekerheid en SRGR; invloed Nederland groot, want relatief weinig bilaterale donoren; enkele gelijkgezinde donoren gaan weg, dus risico op (bilaterale) 'donor wees'; relatief goede score op bestuur (voortgang hervormingen traag, maar politieke wil om bijvoorbeeld corruptie te bestrijden is aanwezig); redelijk goede bijdrage aan eigen ontwikkeling (belastingheffing).

**Ethiopië**
Zeer laag inkomen ($ 330); mogelijkheden voor thema's water, voedselzekerheid, SRGR en veiligheid; Nederland één van de vele donoren en invloed op regeringsbeleid beperkt, wel brede waardering in Ethiopië voor Nederlandse inzet vanwege innovatieve karakter en betrokkenheid bedrijfsleven (dit onderscheidt Nederland van andere donoren); vooruitgang in corruptiebestrijding, politieke vrijheden blijven beperkt (NGO wetgeving); eigen bijdrage aan ontwikkeling via belastingheffing nog gering vanwege smalle basis economie, wel goede ontwikkelingsresultaten en uitvoerende bestuurskracht; cruciale rol Ethiopië in de Hoorn van Afrika; van belang vanuit economisch en veiligheidsperspectief.

**Mali**
Laag inkomen ($ 680); mogelijkheden voor thema's water, voedselzekerheid, SRGR en veiligheid; Nederland is één van de grootste en langst aanwezige bilaterale donoren, Nederland heeft hierdoor goede invloed op het regeringsbeleid; zwakke uitvoeringskracht; redelijke score op bestuur (al bestaan er zorgen ten aanzien van corruptie en veiligheid in verband met drugsdoorvoer en AQIM); van belang vanuit veiligheidsperspectief; redelijke bijdrage aan eigen ontwikkeling via belastingheffing, nog smalle basis economie.

**Mozambique**
Zeer laag inkomen ($ 440); mogelijkheden voor thema's water, voedselzekerheid, SRGR en veiligheid; Nederland betrekkelijk grote donor met een omvangrijk Nederlands programma en daardoor relatief veel invloed; redelijke score op bestuur (stevige dialoog donoren-overheid over onder meer corruptie en democratisering); redelijke bijdrage aan eigen ontwikkeling via belastingheffing, nog smalle basis economie; van belang vanuit economisch perspectief.

**Oeganda**
Zeer laag inkomen ($ 460); mogelijkheden voor thema's voedselzekerheid, SRGR en veiligheid; Nederland één van de vele donoren; zorgen m.b.t. bestuur (ondermeer corruptie en politieke vrijheden); redelijke bijdrage aan eigen ontwikkeling via belastingheffing, nog smalle basis economie; positieve rol Oeganda in Grote Meren en Hoorn van Afrika, link met ontwikkelingen in Zuid-Soedan.

**Rwanda**
Zeer laag inkomen ($ 460); mogelijkheden voor thema's water, voedselzekerheid en veiligheid; meerdere donoren actief, Nederland gewaardeerde donor; effectief bestuur met weinig corruptie, wel zorgen ten aanzien van politieke ruimte; redelijke bijdrage aan eigen ontwikkeling via belastingheffing, nog smalle basis economie, zeer goede ontwikkelingsresultaten; van groot (regionaal) belang voor stabiliteit in Grote Meren gebied.

**Profiel 2**

Voor alle profiel 2-landen geldt dat hun bestuurssituatie zorgelijk is. Juist vanwege het belang van veiligheid hier en daar investeert Nederland in deze landen.

**Afghanistan**
Zeer laag inkomen ($ 260); fragiele staat met mogelijkheden voor thema's veiligheid en voedselzekerheid, uitvoering 3D-benadering; vele donoren, omvangrijk Nederlands programma; belastinginkomsten zeer laag; van belang vanwege regionale stabiliteit en veiligheid hier en daar.

**Burundi**
Zeer laag inkomen ($150), fragiele staat met mogelijkheden voor thema's voedselzekerheid en veiligheid, uitvoering 3D-benadering; klein aantal donoren, Nederland één van de grootste donoren; bestuurssituatie zorgelijk; redelijke bijdrage aan eigen ontwikkeling via belastingheffing, nog zeer smalle basis economie; van belang vanwege stabiliteit en veiligheid in Grote Meren regio.

**Jemen**
Laag middeninkomenland ($ 1060); mogelijkheden voor thema's water, voedselzekerheid, SRGR en veiligheid; Nederland belangrijke donor; ook van belang vanuit veiligheidsperspectief regionaal en in Europa.

**Palestijnse Autoriteiten**
Laag middeninkomenland ($ 1250); mogelijkheden voor thema's water, voedselzekerheid en veiligheid; vele donoren; van belang in het kader van MOVP.

**Soedan** (Zuid-Soedan)
Laag middeninkomenland (Noord-en Zuid-Soedan samen: $ 1220); mogelijkheden voor thema's water, voedselzekerheid, veiligheid en SRGR; weinig donoren; bestuurssituatie zorgelijk; belastingheffing zeer laag; cruciaal in kader van vrede, veiligheid en stabiliteit in de regio.

**Profiel 3**

**Bangladesh**
(Nog) Laag inkomen ($ 590), maar gestaag groeiende economie (wordt gezien als nieuwe opkomende markt – daarom van belang vanuit economisch perspectief); mogelijkheden op thema's water, voedselzekerheid en SRGR; niet hulpafhankelijk dus

invloed Nederland op beleid beperkt; zorgen over bestuurssituatie (ondermeer corruptie en mensenrechten); beperkte bijdrage aan eigen ontwikkeling via belastingheffing.

**Ghana**
Laag inkomen ($ 700, maar volgens meer recente cijfers, inmiddels laag middeninkomenland); mogelijkheden op thema's water, voedselzekerheid en SRGR; Nederland gewaardeerde donor; goed bestuur; via belastingheffing zeer goede bijdrage aan eigen ontwikkeling; van belang vanuit economisch perspectief.

**Kenia**
Laag inkomen ($ 770); mogelijkheden voor thema's water, voedselzekerheid en veiligheid; Nederland één van de vele donoren en geen rechtstreekse samenwerking met de overheid; zorgen over bestuurssituatie (o.a. corruptie); redelijk goede bijdrage aan eigen ontwikkeling (belastingheffing); van belang vanuit economisch en veiligheidsperspectief (o.a. piraterij).

**Indonesië**
Laag middeninkomenland ($ 2230); mogelijkheden voor thema's water, voedselzekerheid, SRGR en veiligheid; bijzondere relatie met Nederland en goede positionering Nederlands bedrijfsleven; corruptie zorgelijk; redelijk goede bijdrage aan eigen ontwikkeling (belastingheffing), brede belangstelling in Nederland.

**Transitiefaciliteit**

**Colombia**
Hoog middeninkomenland ($4990); niet ODA-afhankelijk; snel groeiende economie; goed ondernemingsklimaat en politiek-economisch beleid, vrijhandelsakkoord met EU is getekend – daarom van belang vanuit economisch perspectief; van belang voor stabiliteit van de regio vanwege intern conflict en drugsproblematiek.

**Vietnam**
Laag middeninkomenland ($1010); niet ODA-afhankelijk; voortzetting samenwerkingsrelatie via intensivering economische betrekkingen; belangstelling van/voor Nederlands bedrijfsleven: van belang vanuit economisch perspectief.

**Zuid-Afrika**
Hoog middeninkomenland ($5770); niet-ODA afhankelijk; zeer goede bijdrage aan eigen ontwikkeling; veel mogelijkheden op handels- en investeringsgebied en andere relaties met Nederland; in politiek opzicht voor Nederland in Afrika belangrijk.

# ANNEX III

# IP PROTECTION, MANAGEMENT AND APPLICATION MODELS

# ANNEX III

# IP PROTECTION, MANAGEMENT AND APPLICATION MODELS

## 1. Introduction

Decisions concerning the exploitation of intellectual property have significant bearing on whether or not such IP is available for use by society or is solely commercialised for financial gain. There are many ways in which intellectual property can be exploited to achieve a given set of desired outcomes. This Annex sets out to provide a high level overview of the different technology transfer models in common use, their pros and cons and the situations where one model is used over another.

## 2. An Overview on Patents

Patents confer to the owner exclusive rights preventing any other individual from making, using or selling the protected product or process. This exclusive right gives the patent owner the option of assigning or licensing the rights in part or whole to others.

In a simple decision-making model, entities have four options to consider in respect of patent protection and licensing. These are:[92,1]

i. Patent and license
ii. Patent and not license
iii. Not patent and license
iv. Not patent and not license

The option selected is influenced by a number of factors including:

- Whether an invention is in fact patentable or not as determined by the subject matter, novelty, obviousness and usefulness.
- The benefits of patenting against the opportunity cost and patent application and maintenance costs. Often, there is much speculation on the usefulness or potential market for products or services that could be derived from exploiting a given patent and one expects that the value derived outweighs the patent costs.
- The risk of not patenting. Another party may patent instead which will affect one's freedom to operate.
- The effectiveness of the patent to ensure protection and freedom to operate.
- The ability to enforce patent rights and therefore, defend the patent in the case of infringement, if accused.
- The ability to afford litigation cases.

[1] Not to be confused with what makes an invention patentable or not.

## 3. Complex vs. Discrete Technologies

The patent model assumes that an innovator acquires ownership of the only patent covering a single product. This is the case with a simple or discrete technology and in this case the patent holder does not need to license in or out a patent right in order to produce an innovation.[2] Where technologies are complex, this property right model becomes more complex and in many cases, ownership of a product's technology is shared, thus making it non-exclusive. Patent clusters or thickets are formed when the claims of two or more patents overlap and therefore an inventor does not possess all relevant patent rights to produce the technology. To commercialise the technology, it is necessary for the owner of a technology to enter into negotiations with all other patent holders that own a relevant patent right. The co-operative arrangement, which effectively acts like a patent pool, allows owners of several patents, all of which are necessary for the development of the final product or process, to licence or assign their rights at a single price. Patent pools help to reduce licence transaction costs, distribute risks among the members of the pool and foster better exchange of information. That said, patent pools do not correct all problems associated with a group of related patents. If, in the basket of patents, there is at least one unique blocking patent right in the patent group, the owner of the blocking patent can retard innovation by preventing the commercialisation of complementary patents in the patent group.[3] Due to the anti-competitive nature of patent thickets, they could decrease the level of innovation and competition in a particular market.

Complex technologies are characterised by inter-related features comprising co-dependence, complexity and collaborative networks. For instance, the ART-A alogarithm fits into this description in that it is a complex multi-component technology whose IP resides in a product and process that consists of:

- a simplified patient sample collection using blood dried onto paper (dried blood spots)
- Optimised methods for extracting and purifying the genetic material
- Optimising more affordable and reliable sequencing techniques as well as gene sequence, alignment and base calling software.

To add to the complexity, the IP landscape surrounding the ART-A technologies includes a collection of existing patents and therefore licenses to use technology from third parties may also be required. As a result, the ART-A project may have to create a patent-pool type arrangement in order to be able to freely commercialise the technology it develops, especially outside Africa.

## 4. Patent Pools

A patent pool[4] is an agreement between two or more patent owners to license one or more of their patents as a package to one another or to third parties. The royalties derived from the license can be paid by a licensee directly to the patent holders (licensors) or indirectly

[2] Tilburg University. <http://www.tilburguniversity.nl/tilec/events/conferences/18122009/vandamme.pdf> (Cited: 10 August 2010).
[3] Rodriguez, V. Patent Pools: Intellectual Property Rights and Competition. The Open AIDS Journal. 2010, Vol. 4.
[4] Van Overwalle et al., Dealing with patent fragmentation in ICT and genetics: Patent pools and clearing houses. [Online] 04 June 2007. < http://firstmonday.org/htbin/cgiwrap/bin/ojs/index.php/fm/article/view/1912/1794> (Cited: 02 August 2010).

to an entity (third party) specifically set up for administering the pool. Figure 1 below illustrates this concept. A patent pool allows interested parties (potential licencees) to gather in one instance all the necessary tools to exploit a certain technology i.e. a "one-stop license" rather than obtaining licenses from each patent owner (licensor) individually.[5] An important pre-requisite of patent pooling is voluntary participation of all patent holders. This is in contrast to compulsory licensing which is intended for obtaining access to technology where patent holders do not voluntarily choose to enter into licensing negotiations. The second important pre-requisite is compliance with Competition Law, particularly when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in the relevant market were it not for the patent pooling arrangements.

A comparative illustration of the different licenses needed in a patent pool is presented. P1–P4 represents the patent holders and L1–L4 represents the licensees. In the absence of a patent pool, licensees have to enter into negotiations with all the patent holders, which is a time consuming and expensive process. By contrast, in the presence of a patent pool licensees turn to the patent pool for acquiring the rights as one package, which results in simplification and a significant reduction of transaction costs.

In a patent pool, patent holders decide whether to join forces and form a pool, or a pool can be conceptualised by a third party who approaches the patent holders to contribute patents to the pool. The pool's charter specifies the conditions of the license such as (a) whether independent licensing (in which case individual patent-holders are free to grant licenses on their patents, possibly combined with follow-up innovations), (b) grant backs,[6,7] or (c) reach through clauses are allowed.[8,9]

[5] Overwalle, G Van ed. Gene Patents and Collaborative Licensing models: Patent Pools, Clearinghouses, open Source Models and Liability Regimce. s.l. : Cambridge University Press, 2009.

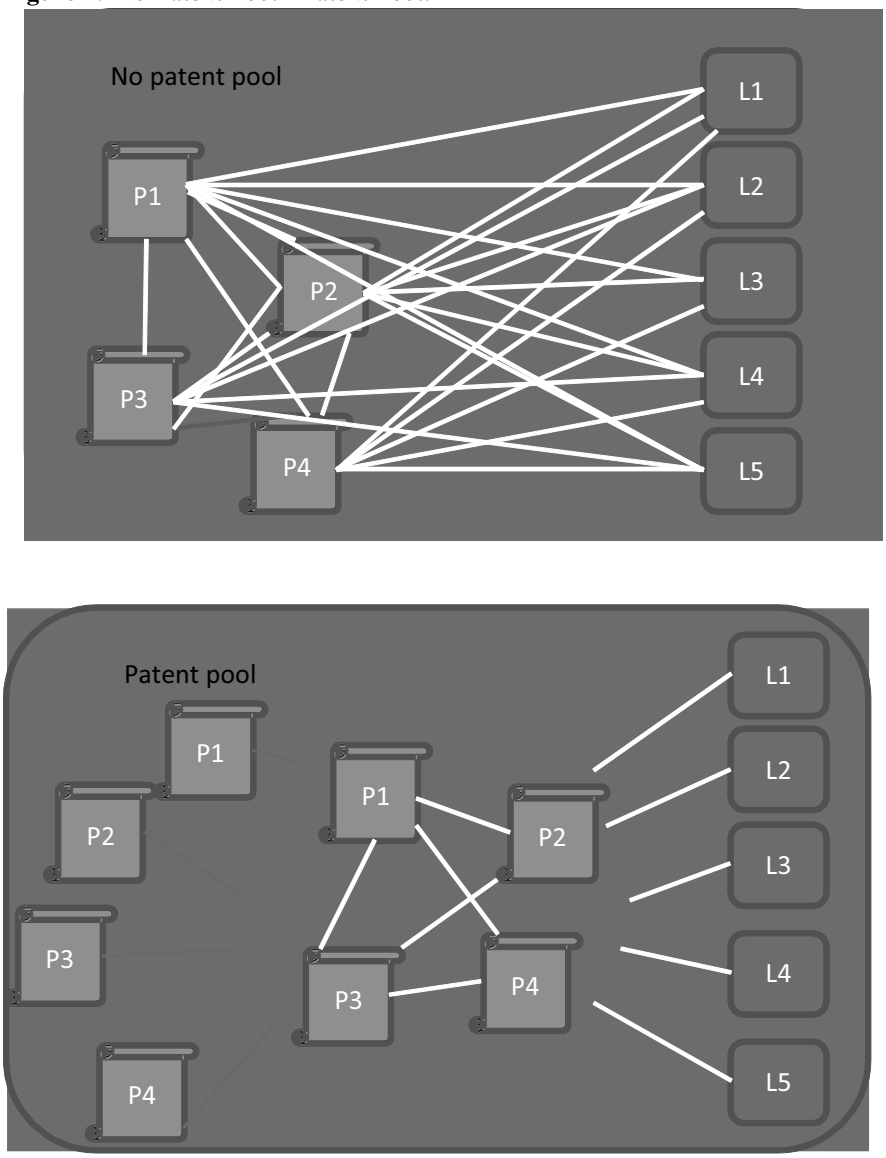
[6] Grant backs are provisions made in a licensing agreement under which the licensee is required to disclose and transfer all improvements made, including related know-how acquired, in the licensed technology during the licensing period

[7] Josh Lerner, Marcin Strojwas, Jean Tirole, 'The design of patent pools: the determinants of licensing rules', *RAND Journal of Economics*, 2007, AUTM.

[8] Reach-through licensing agreements grant the owner of a patent on an upstream research tool the right to receive consideration based on sales or usage of a subsequent downstream product created with that tool. For example, a reach-through licensing agreement might allow a pharmaceutical company to use a patented research tool to identify components of what becomes a marketable drug without paying royalties to the tool owner before commercialization of the product. Rather, the research tool owner would opt to "reach through" and receive a royalty based on a percentage of the drug's future sales.

[9] < http://www.justice.gov/atr/public/hearings/ip/chapter_4.htm#iv> (Accessed 14 February 2011).

**Figure 1:** ***No Patent Pool - Patent Pool.***




*Adapted from Van Overwalle, 2009*[10]

Furthermore, a patent pool can either be open or closed. Where two or more firms combine to license patents to third parties it is called an "open" pool. In the case of three

[10] Birgit Verbeure, 'Patent Pooling for Gene-based Diagnostic Testing: Conceptual Framework', in: Van Overwalle, G., (ed*), Gene Patents and Collaborative Licensing models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, Cambridge University Press, 2009, p. 5.

with fair competition laws. In addition to the examples provided above, several other types of arrangements may exist such as:

- Simple cross-license arrangements between two firms, where there is no clearly stated intention of engaging in future licensing transactions.(e.g. the right to use a software license for business purposes)
- New operating companies that are established to manufacture products based on intellectual property of a number of firms. The different firms contribute their IP to form a patent pool administered by a holding company.
- Firms that acquired large amounts of patents and then licensed them to other concerns (e.g., IBM and other "patent consolidators").
- Pools that are dominated by non-profit entities (e.g. universities, government institutions), where profit-maximizing considerations may not be paramount.

There are pros and cons to patent pools which will be explored next. Patent pools are more effective in a situation where the patents held by the different owners overlap or are interconnected and furthermore, when the key patent holders are included in the pool. Such key players do not have to be deep-pocketed corporations.[11] Smaller companies that hold critical IP can use patent pools to gain critical mass and greater leverage to negotiate for a more favourable position.

The next section looks at the pros and cons of patent pooling.

### 4.1. Pros

- The major advantage to patent pooling is that it lowers transaction costs in cases where access to licenses from more than one patent holder (licensor) is required. It not only reduces litigation between two parties who, in the absence of the pool, would otherwise be infringers but also reduces the expense of negotiating with a myriad of patent holders. The licensing transaction costs are reduced by the "one stop licensing" system.[95] Furthermore, on-going adjustments to the arrangements, decreases substantially as the parties develop a culture of working together. This is a benefit that goes to those inside the pool as well as the rest of the industry.[12]
- Patent pools provide opportunity for knowledge exchange between institutions. Technical information which would otherwise have been guarded as trade secret as well as know how is shared among members of the pool as working relationships between members of the pool improve and technologies are being developed in cooperation. It is this exchange that in turn facilitates further innovation and efficient use of resources.
- Patent pools are able to serve as a clearing of blocking patents (patents that would be infringed when practicing another patent) provided the blocking patents are included in the pool. Owners of patents that provide the basic building blocks of an industry may create blocking patents. For instance, a granting of patents on DNA sequences for proteins.

[11] Closon, Kevin. Patent pools: Are they right for your business. <http://www.nerac.com/img/patent_pools_spie_professional.pdf> (Cited: 02 August 2010).
[12] Clark, Jeanne, Stanton, Brian, Tyson, Karin. Patent Pools: A Solution to Problem of Access in Biotechnology Patents. <http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf> (Cited: 06 December 2010).

- Patent pools enable the management of multiple owners and eliminate problems associated with stacking[13] of royalties. Royalty stacking refers to situations whereby a single product potentially infringes on many patents, and thus may bear multiple royalty burdens.[14]
- Pools facilitate professional management of the negotiation and administration of licensing arrangements, which may be of particular benefit to smaller entities who may not have such well developed capacities.
- They offer a reduction of infringement litigation costs in that license owners that would be infringed upon if they did not belong to the pool are part of the pool and work within n agreed framework of cooperation with licensees.
- Patent pools have the potential to encompass non-patent technology and know-how. As technologies are applied in different environments, new knowledge is generated all the time and it is this new knowledge that leads to new know-how, further innovation and improvements to the technology.
- Patent pools provide the potential to facilitate technology transfer and a sustainable scaling up of capacity and access in the developing world, e.g. the UNITAID HIV Medicines Patent Pool which is discussed at the end of this chapter.
- Finally, patent pools usually accompany the establishment of industry standards which is useful to participants and non-participants alike. For example, the recent patent pool encompassing MPEG-2 technology led to the rapid formation of a standardised protocol to protect copyrighted works on the Internet.[95,99]

### 4.2. Cons

- Patent pools are not easy to form and, with the different interests in the group, can be extremely costly to administer.
- Where a patent pool comprises a significant number of patents, there is a risk of shielding invalid or invaluable patents. This may lead to inequitable remunerations.
- Another concern is the possibility of patent pooling promoting collusion among patent owners, either among owners of competing intellectual property or among firms that manufacture products using the patented technology.[15] The result of such tactics would be considered unfair competition practices by other the industry players.
- A fourth concern is that a patent pool, particularly a patent pool that is associated with the establishment of an industry standard, may foreclose competition relative to an alternative patent pool that allows access to needed patents at lower, less discriminatory royalty rates. Patent pools should avoid causing anti–competitive restraints and will most likely be accepted if they meet a series of conditions such as providing validity and essentiality of the patent as determined by an independent expert; non-exclusive licensing to the pool; freedom to develop alternative technologies; grantback provisions; royalty allocation formula; fair, reasonable and non-discriminatory royalty payment arrangements; safeguards for sensitive business information; and, dispute resolution mechanisms.[95]

[13] Royalty stacking occurs when several different parties own the IP necessary to get a product to the market and they all demand royalty payments from the ultimate seller of the product in question.
[14] Lemley, M.A, Shapiro, C. Patent Holdup and Royalty Stacking.
<http://faculty.haas.berkeley.edu/shapiro/stacking.pdf> (Cited: 06 December 2010).
[15] Nelson, Philip B, 'Patent Pools and Economic Assessment of Current Law and Policy',
<http://org.law.rutgers.edu/publications/lawjournal/38-2/07NelsonVol.38.2.pdf> (Cited: 02 August 2010).

Concerns over the anti-competitive effects and consequences of patent pooling include:

- Combining intellectual properties with the consequence of violating antitrust laws (intentionally or otherwise)
- The further effects on competition when combined intellectual properties are accepted as industry standards
- Cross-licensing of intellectual property within the pool potentially resulting in price-fixing and anticompetitive exclusionary practices that undermine competition in the market
- Bundling of intellectual rights to long term business transactions or agreements to extend the market exclusiveness of intellectual rights beyond their statutory duration.
- Trade secrets, if they remain undisclosed, and as a result, having an eternal length of life.[16]
- Grant-back clauses whereby any technology that is an improvement on the original patent is licensed back to the patent pool.[17] In this instance, the grant-back could take away an incentive to improve upon the technology, as it may be difficult for companies to control their new intellectual due to the grant-back requirement. A reasonable grant-back clause should be limited to patents that could affect the original mode and original use of the technology and not material changes to the technology.

In the USA, the Department of Justice and the Federal Trade Commission have established Antitrust Guidelines for the Licensing of Intellectual Property.[18] In the EU, similar competition rules are incorporated into the EC Treaty and complemented by a series of legislation.[19] The Guidelines recognise that licensing, cross-licensing, or otherwise transferring intellectual property can facilitate integration of the licensed property with complementary factors of production. Such integration can benefit consumers through reduction of costs and the introduction of new products. The Guidelines also caution, however, that "while intellectual property licensing arrangements are typically welfare-enhancing and precompetitive, antitrust concerns may nonetheless arise particularly when a licensing arrangement harms competition among entities that would have been actual or likely potential competitors in a relevant market in the absence of the license."[20] In essence, the Guidelines seek to ensure that by creating a patent pool, participants of the pool do not gain a level of power or collude in a manner that results in unfair competition for enterprises that are not part of that pool.

[16] <http://en.wikipedia.org/wiki/Competition_law> (Cited: 19 April 2010).
[17] Kulbaski, J., 'Comments On Patent Pools and Standards For Federal Trade Commission Hearings Regarding Competition & Intellectual Property'. <http://www.ftc.gov/opp/intellect/020417jamesjkulbaski.pdf >(Cited 14 February 2011).
[18] Federal Trade Commission, 'Federal Trade Commission and Department of Justice Issue Report on Antitrust and Intellectual Property'.17 April 2007.
<http://www.ftc.gov/reports/innovation/P040101PromotingInnovationandCompetitionrpt0704.pdf > (Cited: 15 October 2010).
[19] Intellectual Property Rights and Competition Policy. <http://www.scribd.com/doc/17231299/Intellectual-Property-Laws-and-Competition-Policy> (Cited 21 February 2011).
[20] Love, James, 'Essential Inventions, Inc. on Collective Management of IP Rights: Patent Pool'. [Online] 08 July 2002. <http://www.essentialinventions.org/docs/eppa/whatisapatentpool.html> (Cited: 10 April 2010).

### 4.3 Examples of Patent Pools

An example of patent pooling in the software environment involves Linux, which has established a patent pool as a means of defense. Linux is an operating system developed under the GNU[21] Project, and is an example of free software and open source development, which means that the source code is available for anyone to download, modify and re-issue.[22] David Serafino from Knowledge Ecology International[107] states that

"*The end goal of the Open Invention Network (OIN) is to create "a system under which companies will make substantial investments in Linux without any worries regarding intellectual property issues, and under which companies can embed, repackage, and use Linux to create complementary products" the end goal of which is to facilitate innovation in any field able to make use of the technology."*

Related to the OIN is the Open patent movement which seeks to build a portfolio of patented inventions that can be freely distributed under a copy left-like license.[23] The basic idea behind OpenPatents.org is to change the rules of the patent game such that it is to the advantage of participants to help solve the problems of software patents. Users who have accepted the license can use works as is, or improve them, in which case the patent improvement would have to be re-licensed to the institution that holds the original patent, and from which the original work was licensed. OIN will license any patent, royalty-free, with the only stipulation being that licensees refrain from asserting their own patents against the Linux environment.

According to the literature, large organisations such as Nokia, Apple and Phillips have developed successful Open Innovation models where their ability to access networks has resulted in the creation of new revenue streams.[24][25] In contrast, similar benefits have not been realised by small innovative firms largely because the smaller firms lack the resource capability, skills and knowledge to effectively and safely outsource their innovation processes.

**Box ANNEX III-1:** ***Example: Patent pool for HIV drugs***

*Given the context of the ART-Aprogramme, it is important to mention the HIV drugs Medicines Patent Pool established in 2009 through the support of UNITAID.[26] The pool, which started operating in mid-2010, aims to make newer medicines available in patient-adapted form, at lower prices, for low-*

[21] Stallman, Richard, 'The GNU project was launched in September' . [Online] September 1983. <www.fact-index.com/g/gn/gnu.html > (Cited: 04 April 2010).
[22] Serafino, D., 'Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures'. [Online] 4 June 2007. <http://www.keionline.org/misc-docs/ds-patentpools.pdf > (Cited: 19 April 2010).
[23] Copyleft is a terms that describes the practice of using copyright law to offer the right to distribute copies and modified versions of a work and requiring that the same rights be preserved in modified versions of the work. In other words, copyleft is a general method for making a program (or other work) free, and requiring all modified and extended versions of the program to be free as well.
[24] Open Innovation. <http://www.scribd.com/doc/430077/Open-Innovation> (Cited 21 February 2011).
[25] Hall, B.H., *Open Innovation and Intellectual Property Rights: A Two Edged Sword.* <http://elsa.berkeley.edu/~bhhall/papers/BHH09_IPR_openinnovation.pdf> (Cited 21 February 2011).
[26] UNITAID. 'UNITAID Approves Patent Pool'. <http://www.unitaid.eu/en/20091215237/News/UNITAID-APPROVES-PATENT-POOL.html> (Cited: 15 October 2010).

*and middle-income countries. The Patent Pool will allow generic companies to make lower cost versions of widely patented new medicines by creating a common space for patent holders to license their technology in exchange for royalties.* [27,28] *This is expected to spur competition and further bring down the price of vital new and effective medicines. Medicines targeted for the pool include those that are either too expensive due to a lack of competition or are not adapted to the specific needs of resource-limited settings in developing countries (e.g. requiring refrigeration). In addition, medicines that exist, but for which fixed-dose combinations have not yet been developed, drugs that are not yet available on the market, or those that are still under development are included in the pool. The Medicines Patent Pool has identified 19 products from nine companies for potential inclusion into the pool, which will facilitate the development of fixed-dose combinations (FDCs). For some years now clinical evidence has revealed that these combinations are the best way for patients to access safe, effective treatment. However, until now, patents have created barriers to developing FDCs combining newer and more effective drugs from different companies. The Medicines Patent Pool has had to ensure that the patent pool works in a way that is consistent with other multilateral mechanisms that provide access to medicines – such as the World Trade Organization declaration on the Trade-Related Aspects of Intellectual Property Rights agreement and public health; the World Intellectual Property Organization development agenda, and the WHO strategy on public health innovation and intellectual property. While it is widely acknowledged that the UNITAID Medicines Patent Pool is a noble and pioneering effort to improve access to cheaper and better medicines for HIV and AIDS, the build up to the initiative has been a slow. It is as recent as September 2010 that the U.S. National Institutes of Health (NIH) became the first patent-holder to share its intellectual property when it licensed Darunavir to the pool.*[29] *Following this move, Medicines Patent Pool anticipates that more agreements with other patent holders will follow in the months to follow.*

*At this point, it is also worth mentioning ViiV Healthcare, a recent new player in the HIV/AIDS treatment and care area that has the potential to make a significant impact in the field.*[30] *ViiV is a global specialist HIV company established by GlaxoSmithKline and Pfizer to deliver advances in the treatment and care for people living with HIV. The company, which was launched in November 2009, aims to take a deeper and broader interest in HIV/AIDS than has been done before and take a new approach to delivering effective and new HIV medicines as well as support communities affected by HIV.*

[27] Sreelata, M. 'Patent pool decision heralds era of cheap HIV Drugs'. [Online] 16 March 2010. <http://www.scidev.net/en/news/patent-pool-decision-heralds-era-of-cheap-hiv-drugs.html> (Cited: 03 May 2010)

[28] International HIV AIDS Alliance. 'Alliance welcomes creation of a HIV patent pool'. [Online] 18 December 2009. <http://www.aidsalliance.org/newsdetails.aspx?id=453> (Cited: 03 May 2010).

[29] <http://www.ghdonline.org/hivprevention/discussion/dirunavir-1st-patent-licensed-to-medicines-patent-/ > (Cited: 07 December 2010).

[30] <http://www.viivhealthcare.com/> (Cited: 07 December 2010).

## 5. Clearing-house Mechanism

The term clearing house is used to promote the advertising, discovery, access, dissemination and use of information and data held by numerous organisations using the decentralized capabilities of the Internet.[31] In its simplest definition, a clearing-house can be viewed as a "network of networks". More recently, the concept has acquired a much

broader meaning and is used to describe almost any mechanism whereby providers and users of goods, services and/or information are matched. Figure 2 below illustrates the clearing house model.

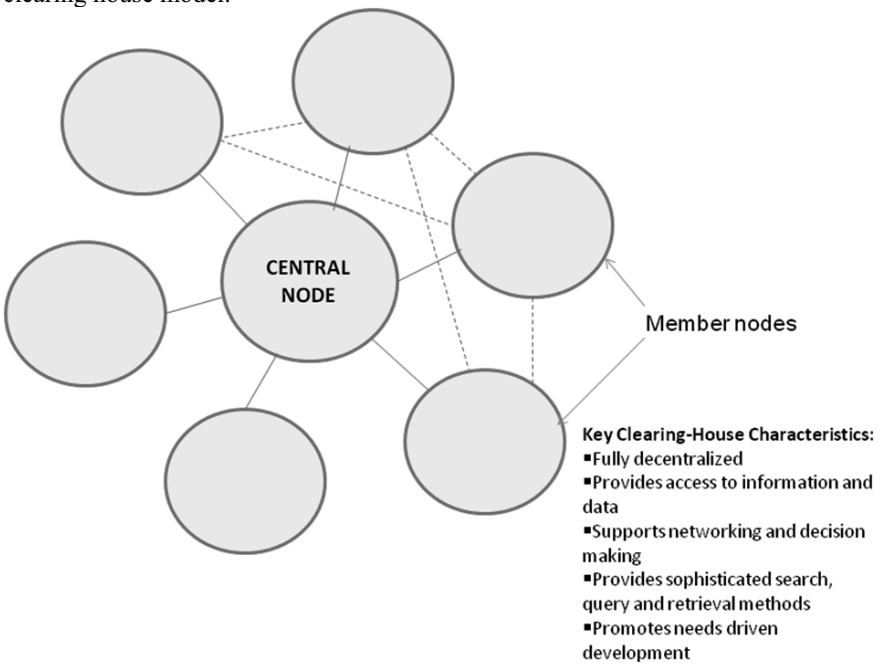



**Figure 2:** ***Clearing House model***

There are five types of clearing houses that have been identified.[32] The first two models merely provide access to (protected or not easily accessible) information. This might be basic information related to the technology, the patents, or claims covering these technologies (information clearing house) and/or lists of technologies available through licensing, thereby providing a platform for technology owners and users to enter into bilateral negotiations (technology exchange clearing house).

(i) The **information clearing house** provides a mechanism for the exchange of technical knowledge and/or information related to its intellectual property status. Information mechanisms are relatively easy to set up but require constant maintenance and

[31] GPA Clearing-House Mechanism: Overview. [Online] January 2001. <<http://dinrac.nowpap.org/documents/GPA_CHM_Overview_&_Status.pdf> (Cited: 19 April 2010).

[32] E. van Zimmeren, B. Verbeure, G. Matthijs and G. Van Overwalle, ' A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?', *Bull World Health Organ,* 2006, Vol. 84, p. 5.

updating.[109] Examples include general patent search sites, either freely accessible, such as Espacenet from the European Patent Office (EPO), or fee-based, like Delphion, STN International, Dialog or Micropatent.

(ii) The **technology exchange clearing house** is inspired by the basic Internet business-to-business (B2B) model. This type of clearing house offers an information service that lists available inventions. These lists allow buyers to initiate negotiations for a licence. Furthermore, partnering, mediating and managing facilities may be provided.[105] The technology exchange clearing house model is, in general, cheaper to maintain and relatively inexpensive to operate. However, it might be difficult to bring together a large enough number of patents to establish the clearing house as a useful tool that ensures effective access to a comprehensive body of patented inventions. At present, most clearing houses only offer a small proportion of the market and a low density of patents, and one has to search several web sites, some of which impose considerable registration fees. Moreover, this model might only be suitable for technologies that can be easily defined and valued: for example, general purpose research methods, such as PCR, and for patents protecting very specific and well defined improvements to familiar upstream products or processes.

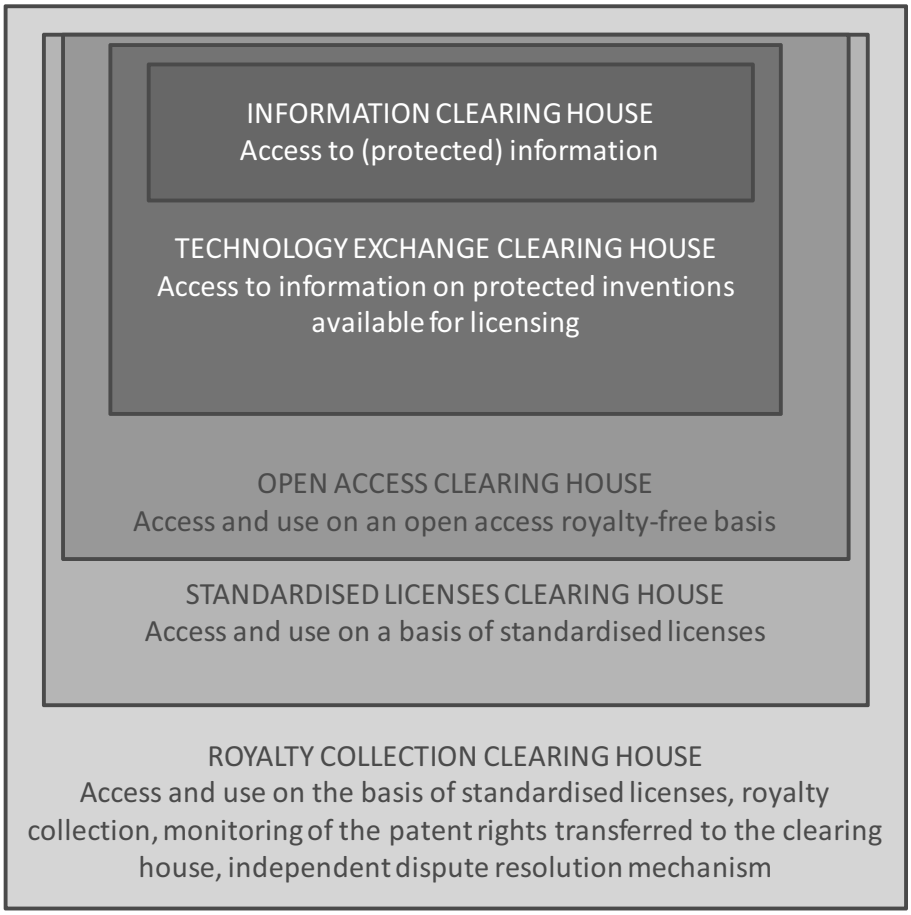
In the case of the technology clearing house model, actual access to the patented inventions is not usually granted by the technology exchange clearing house but by the individual patent holder after one-to-one licensing negotiations have taken place with the licensee. These negotiations are, however, based on the information on the inventions which was provided by the clearing house.

The remaining three models are more advanced clearing house types that aim to not only provide access, but also to standardise the use of patented inventions. Access and use can be offered by a clearing house on a royalty-free open-access basis (open access clearing house), or via standardised licences (standardised licences clearing house and royalty collection clearing house). In addition to providing standardised licences, a royalty collection clearing house may offer monitoring of the patents transferred to the clearing house and an independent dispute resolution mechanism. Figure 3 below provides a comprehensive illustration of the different models.

The first type of the advanced clearing house models is the open access clearing house. This type of clearing house does not only foster free access to information about inventions, but also offers standardised free use of inventions. A well known example in the life sciences is the SNP Consortium. The goal of the non-profit SNP Consortium is to identify and collect single nucleotide polymorphisms (SNPs) and create and make the SNP map of the human genome publicly available, without any proprietary rights, in order to enable further drug discovery.

Open access clearing houses may be particularly well suited to sharing and exchanging unpatented inventions. However, most of the genetic inventions are the result of long and expensive research initiatives. Both private enterprises and universities usually seek to recover their investments in such research and, therefore, apply for patent protection.

**Figure 3:** ***Types of clearing houses***[33]




An upcoming model in this series is the clearing house that provides access to standardised licences for the use of protected inventions, hereinafter called the **"standardised licences clearing house".** An example of this scheme is **Science Commons**. [109,34] This organisation aims to encourage data sharing, technology transfer and intellectual property licensing, by stimulating stakeholders to adopt standardised licences in order to create greater transparency. Its sister organisation, **Creative Commons**, has already been in operation for many years facilitating the use of copyrighted material (such as music, movies, photos, books, course materials, scientific literature (e.g. PLoS Biology)) by way of standardised, simplified licences and it has been very successful.[35]

[33] Esther van Zimmeren, 'Clearinghouse Mechanisms in Genetic Diagnostics: Conceptual Framework', in: Van Overwalle, G., (ed*), Gene Patents and Collaborative Licensing models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes*, Cambridge University Press, 2009, p. 80.

[34] <http://sciencecommons.org/projects/licensing/> (Cited 06 December 2010).

[35] Geertrui van Overwalle, Esther van Zimmeren, Birgit Verbeure, Gert Matthijs. 'Dealing with Patent Fragmentation in ICT and Genetics: Patent Pools and Clearing Houses', *First Monday*, 2007, Vol. 12, 6.

Finally, the **royalty collection clearing house** comprises all the functions of the information clearing house, the technology exchange clearing house and the standardized licences scheme (Fig. 3). In addition to these functions, the royalty collection clearing house sets up a mechanism to cash licence fees from users on behalf of the patent holders in return for the access to and use of the inventions. The patent holders will be reimbursed by the clearing house in accordance with a set allocation formula. Royalty collection clearing houses vary with respect to their make-up, in particular their legal basis, legal structure, decision-making procedures, price-setting procedures, and licensing conditions. In general, however, they are subject to competition law. Therefore, they should refrain from discriminatory practices and set reasonable prices.[36]

An important prerequisite for the royalty collection clearing house to be effective is that there should be a continuous and ongoing demand for patents included in the clearing house. Moreover, the establishment of this type of clearing house is only worthwhile if many patent holders or an entire branch of industry participates. It remains to be seen whether patent proprietors with a strong portfolio would be willing to voluntarily participate in such a clearing house.

At present, no examples of a royalty collection clearing house exist in the field of patents. The Global Bio-Collecting Society (GBS) was a praiseworthy attempt to design a royalty collection clearing house model in life sciences.[109] It was designed to function as an efficient, fair and equitable exchange model of indigenous knowledge between knowledge holders (indigenous groups) and knowledge users (life science industry). The GBS model was never realised, probably because traditional knowledge is a highly sensitive issue, and no consensus could be reached among the stakeholders, nor was there the necessary political support. The GBS model was devised to encourage arrangements between indigenous groups (who generally did not hold any intellectual property rights) and private and public entities (who did have intellectual property rights) to clear controversies with respect to biodiversity and indigenous knowledge. However, the model might also be applicable to the more classic intellectual property relationship between patent holders (licensors) and users of the patented inventions (licensees).

## 6. Creative Commons and Open Source[37]

Open licensing is a concept borrowed from free software licensing. The release of raw research results into the public domain can play equally as influential a role in dissemination of knowledge as patenting (if not more so). There are a number of advantages to be gained by putting this information in the public domain: first, it reinforces the norm of open science; second, it provides an alternative to expensive proprietary information databases; and third, it effectively excludes the patenting option until some additional step is taken.

[36] Esther van Zimmeren, Birgit Verbeure, Gert Matthijs, Geertrui Van Overwalle, 'A clearing house for diagnostic testing: the solution to ensure access to and use of patented genetic inventions?', *Bull World Health Organ*, 2006, Vol. 84, p. 5.

[37] Nicol, Dianne, 'Strategies for dissemination of university knowledge'. [Online] 1 January 2008. <http://www.thefreelibrary.com/Strategies+for+dissemination+of+university+knowledge-a0200915337> (Cited: 10 August 2010).

The advantages of Open Licensing are:[38]

- It is free for anyone to use and customise as per their needs;
- It allows for a greater degree of flexibility in terms of what can be offered to those who wish to use the content non-commercially, and those who wish to use it commercially;
- It takes a more pragmatic approach that is more cognisant and suited to an online environment;
- It allows for a content owner friendly approach to customisation of licences if required; and
- By its very nature, it tends to encourage an 'open to full view and review' approach to content, with revenue derivation encouraged only for commercial use cases.

Equally, there are concerns regarding Open Licensing. The most common concern is associated with the reliability of the product and support options in the event that the product develops a problem. In such an environment where product development is dispersed over many contributors, it is difficult to police the quality of products. Linked to this is the concern of who is in charge of an open source product and what happens when leading figures associated with the open source product are no longer involved or interested in the product and its maintenance. Other concerns include the incorporation of malware by embedding malicious code into the original open source distribution. Such malware may not only cause undesirable effects, but also compromise the security of the network. Problems also arise where open source code is modified, packaged and distributed. It is not easy to monitor and enforce software license compliance that informs against proprietary ownership of the modified product and its subsequent expolitation. Multiple open source licenses exist and selecting a suitable license is challenging, especially when one is not familiar with the complex legal issues.[39] Furthermore, open source licenses may contain special conditions or choices such as ones listed below. The main consideration is to ensure that derivative works are subject to the same license and that they cannot be made proprietary. Open source licenses need to be looked carefully in light of both the legal issues that may arise under the license and the desire to promote community-oriented approach to development.

Creative Commons licensing model comprises a suite of licenses that provide the creator or rights holder flexibility for both commercial and non-commercial uses on a 'some rights reserved' principle. The choices are:[116]

- *Non-commercial:* the work can be copied and shared as long as the author is identified. Permission is required before any derivative work based on the original work is created or any commercial use is made of the work'.
- *No derivative*: only verbatim copies of the work can be distributed, copied and performed, not derivatives of it.

[38] Singh, Rajesh Sreenivasan and Abhishek, 'Intellectual Property and Licensing of Online Content in Local Asian Nations'. [Online] 22 - 24 January 2007. <http://www.panl10n.net/Presentations/Bhutan/Consultation/IPRandLiscensing.pdf >(Cited: 02 September 2010).

[39] Kennedy, Dennis M, 'A Primer on Open Source Licensing Legal Issues: Copyright, Copyleft, Copyfuture'. <www.iphandbook.org/jforum/posts/downloadAttach/61.page > (Cited 16 February 2011).

- *Share Alike*: the work can be copied, remixed, tweaked and built upon non-commercially. All new work based on the original must also carry same licence conditions. Permission is required for commercial use.
- *Sampling Licenses:* these allow for snippets (not whole work) to be remixed into new works, even commercially.
- *The Developing Nations license:* this license lets you offer less restrictive terms to countries that are not considered high income by the World Bank.

This model may be important in the commercialisation of the ART-A technology as it enables the creator to determine how the content can be distributed.

## 7. Socially Responsible Licensing[40]

The concept of socially responsible licensing was developed at the University of California, Berkeley in 2002.[41] Eva Harris, an associate professor at the School of Public Health, proposed a licensing agreement to Berkeley that would allow the non-profit Sustainable Sciences Institute to develop and distribute the technology to underserved countries for free or at cost, while maintaining the university's right to earn future royalties from derivative technologies distributed in developed countries. Essentially, socially responsible licensing allows the research institution to use the technology for humanitarian purposes or to ensure that the license makes the technology available to defined market segments such as devveloped and developing country markets. Market segmentation options can be based on geographic exclusivity, tiered pricing and mandatory sub-licensing to developing countries to meet specific humanitarian objectives. At the time Harris' proposal was a radical departure from standard licensing models, but it was surprisingly well received by the university. The licensing proposal encouraged Berkeley's technology transfer management office to restructure their valuation process to include the double bottom line concept; a two pronged evaluation of the financial bottom line and the scope of social impact, both being equally important.[42] This new idea of incorporating social impact into considerations around intellectual property rights opened the door to a broad range of IP-management models. From the university's standpoint, the additional revenue that would be gained from marketing in developing countries is not significant, given that they already receive over $50 million in royalties from current licensing agreements. Ultimately, the Berkeley licensing proposal proved to be mutually beneficial to the public and private sectors, achieving the university's social goals without eliminating the profit drivers for a potential private sector partner. Through this legal innovation, it was possible to safeguard the potential distribution of inventions in developing countries on a not-for-profit basis.

The ART-A project is looking into the potential of applying social responsible licensing principles when commercialising the medical diagnostic and asociated IP.

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[40] Imtiazuddin, Maleeha Mohiuddin and Omer. Socially Responsible Licensing:Model Partnerships for Underserved Markets. [Online] March 2007. http://www.acumenfund.org/uploads/assets/documents/Acumen%20Fund%20-%20Socially%20Responsible%20Licensing%20-%20July%202008_kYAIb8kF.pdf (Cited: 02 August 2010).

[41] Socially Responsible Licensing: Model Partnerships for Underserved Markets. [Online] March 2007. <http://www.acumenfund.org/uploads/assets/documents/Acumen%20Fund%20-%20Socially%20Responsible%20Licensing%20-%20July%202008_kYAIb8kF.pdf> (Cited: 15 October 2010).

[42] Bergman, Barry. Research patently in the public interest. [Online] 02 December 2005. <http://berkeley.edu/news/berkeleyan/2005/12/02_licensing.shtml> (Cited: 02 August 2010).

## 8. Royalty Free Licensing

Under the Bayh Dole Act of 1980 the federal government retains certain rights to protect the public interest. [43,44] The act states that the government is provided a "nonexclusive, non-transferable, irrevocable, paid-up license to practice or have practiced for or on behalf of the United States any subject invention throughout the world...." This license, commonly known as a "royalty free license," has been the subject of some discussion including whether or not this permits government purchasers to obtain discounts on products developed from federally funded R&D, particularly pharmaceuticals.

Many of the current concerns about the Bayh-Dole Act primarily arise out of its application to the biotechnology and pharmaceutical industries. Congressional interest in providing lower cost drugs, particularly to seniors, has focused attention on the role the act has had on the development of new pharmaceuticals for the marketplace. Certain critics maintain that the price of many therapeutics derived from federally funded R&D are excessive considering the government's financial contribution to R&D.[45] It is essential at this point to mention the United States federal 'march-in' rights under the Bayh Dole Act. In a march-in situation, the US government can force a compulsory license to a patent derived from federally funded research. The federal government's march-in rights present are a contentious issue because it allows the funding agency, on its own initiative or at the request of a third party, to effectively ignore the exclusivity of a patent awarded under the act and grant additional licenses to other "reasonable applicants". This right is strictly limited and can only be exercised if the agency determines, following an investigation, that one of four criteria is met; the most important of these are a failure by the institution or enterprise to take "effective steps to achieve practical application of the subject invention" or a failure to satisfy "health and safety needs" of consumers. Interestingly, a march-in has never been completed in the thirty or so years of Bayh-Dole, although several attempts have been started. Those that support march-in rights maintain that the American citizen is forced to pay twice for health technologies developed from federal government funding; first through taxpayer funding for R&D and second through costs associated when accessing medical care. The argument against march-in rights is that they discourage businesses from licensing, developing and creating products based on federally funded research. However, given the government's record of never exercising march-in rights for now, the threat to businesses is minimal.

Finally, a royalty-free license may be granted to another non-profit research institute to enable a researcher to practice the invention for research purposes. While these kinds of licenses are can be complex in terms of eventual commercialisation and subsequent payoff, such licensee arrangements are sometimes the most effective at transferring the technology for the public good.

[43] The Bayh Dole Act. [Online] http://www.cptech.org/ip/health/bd/ (Cited: 02 August 2010).
[44] AUTM. The Bayh Dole Act. [Online] <http://www.autm.net/Bayh_Dole_Act/4490.htm> (Cited: 02 August 2010).
[45] Schacht, Wendy, 'Federal R&D, Drug Discovery, and Pricing': [Online] 19 June 2000. <http://www.law.umaryland.edu/marshall/crsreports/crsdocuments/RL30585.pdf> (Cited: 03 May 2010).

# ANNEX IV

# AFRICAN IP ORGANIZATIONS

# ANNEX IV

# AFRICAN IP ORGANIZATIONS

## 1. ARIPO

The African Regional Intellectual Property Organization (ARIPO), formerly African Regional *Industrial* Property Organization, is an intergovernmental organisation for cooperation among African states concerned with processing patent and registered trademarks for member states.[1] ARIPO's 16 member states are mainly English speaking countries and include Uganda but not South Africa. Member states are countries that are the original signatories of the Lusaka Agreement adopted 9 December 1976. Counties that joined after the signing of the Agreement are called observer countries. South Africa is one of 14 countries that have an observer status in ARIPO. [2] The Lusaka Agreement together with the Harare and Banjul protocols, both of which are explained later in this section, constitute ARIPO to handle copyright, industrial design, patent, trademark, traditional knowledge and utility model rights on behalf of member countries.

The objectives of the Organisation, as presented in Article III of the Lusaka Agreement[46], is to attain cooperation in industrial property legislations in order to achieve technological advancement for economic and industrial development of the member states. This cooperation is reflected in the objectives of the Organisation which are to:

(a) promote the harmonisation and development of the industrial property laws, and matters related thereto, appropriate to the needs of its members and of the region as a whole;
(b) foster the establishment of a close relationship between its members in matters relating to industrial property;
(c) establish such common services or organs as may be necessary or desirable for the co-ordination, harmonisation and development of the industrial property activities affecting its members;
(d) establish schemes for the training of staff in the administration of industrial property law;
(e) organise conferences, seminars and other meetings on industrial property matters;
(f) promote the exchange of ideas and experience, research and studies relating to industrial property matters;
(g) promote and evolve a common view and approach of its members on industrial property matters;
(h) assist its members, as appropriate, in the acquisition and development of technology relating to industrial property matters;
(i) do all such other things as may be desirable for the achievement of these objectives.

[1] ARIPO, Agreement on the Creation of the African Regional Intellectual Property Organization (ARIPO). Lusaka: ARIPO, 1976.
[2] C.J. Kiige, 'Trends in the Protection of Intellectual Property in Africa', Mexico: Tequila Regulatory Council, 2009.

### 1.1. Harare Protocol on Patents and Industrial Designs Within the Framework of the African Intellectual Property Organisation

The Harare protocol to the Lusaka agreement was adopted in Zimbabwe in 1982 and last amended in 2006.[47] Uganda is party to this protocol together with 14 other states, excluding South Africa. Signatories to this protocolgive their consent for ARIPO through its Secretariat, to grant patents and to register utility models and industrial designs and to administer such patents, utility models and industrial designs on behalf of the member states in accordance with the provisions of the Protocol. Patent and industrial design application could either be filed directly with ARIPO or through the Intellectual Property Office of the country. Either way, the application will receive the same filing date. The ARIPO also processes PCT applications. All Patent and Industrial Property applications received are examined by ARIPO and the protocol regulations provide detailed information on the registration processes.

### 1.2. Banjul Protocol on Marks

The Banjul protocol to the Lusaka agreement was adopted in November 1993 in Gambia and was last amended in 2004.[46] Uganda is one of 8 countries that are party to this protocol. South Africa is not a party to this protocol. In essence, State parties to the Banjul protocol have entrusted the registration and administration of trademarks to ARIPO. As in the Harare protocol, trademark applications from member countries are either filed directly with ARIPO, which is based in Zimbabwe, who then acts on behalf of the country or they are filed through the Intellectual Property Office of the country concerned who then forwards the application to ARIPO. To this extent, any trademark protection that the ARTA-IP initiative would seek in Uganda would be processed by the ARIPO office. The Banjul regulations would need to be consulted for procedural guidance[3].

**Box ANNEX IV-1*: Mandate on Copyright***

*In 2002, ARIPO member countries adopted a strategic plan designed to extend the mandate of ARIPO to include Copyright and related rights. Key strategic activities that were adopted include: [4]*

1. *Revision of the basic documents of the Organisation, namely the Lusaka Agreement, the Protocol on Patents and Industrial Designs within the Framework of ARIPO (the Harare Protocol) and the Banjul Protocol on Marks;*

2. *Revision of the organisational structure of the Secretariat of ARIPO, to include a*

[3] Link to Banjul Protocol on Marks <http://docs.google.com/viewer?a=v&q=cache:zATuOfbBxqkJ:www.aripo.org/index.php%3Foption%3Dcom_docman%26task%3Ddoc_download%26gid%3D5%26Itemid%3D11+Banjul+protocol&hl=en&pid=bl&srcid=ADGEEShAeGnq4DFldj9g0eB4QbBuC46E_LwEGtOBBBMUDZfCKV4rafRxxiJ85wgu6_PUgTiPAq3HopO1jlcLAnsGIjNiRsL_4IVe3-79DHy8vSax2NNE7TDhZU_hAOhQSt80dv5PTNN&sig=AHIEtbQ-p2iGTdp99qaz77AvB5k7P-gpsQ>

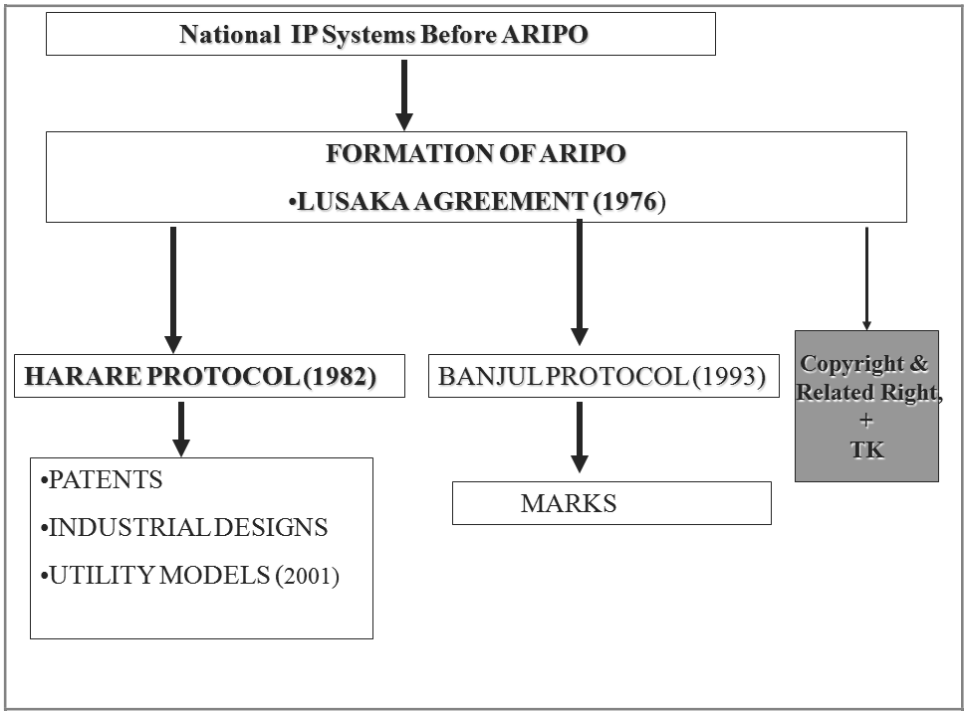
[4] <http://www.inventa-international.com/oapi> (Cited: 01 September 2010).

*Copyright Officer;*

3. *Formulation of policy matters in the field of Copyright and Related Rights that will be the main focus of ARIPO in the short and medium terms;*
4. *Sensitisation of the stakeholders in Member States on the new mandate and the explanation of its practical implementation; and*
5. *Extensive training of members of staff of the Secretariat of the Organisation and officials from Member States, mainly in matters relating Copyright and Related Rights.*

*Today, ARIPO plays an advisory role in respect of Copyright and Related rights.* [49]

**Figure 1:** ***Illustration of ARIPO's IP System***




## 2. OAPI[5]

The Organisation Africaine de la Propriété Intellectuelle or OAPI (English: African Intellectual Property Organisation) was created by the Bangui Agreement of 1977 and subsequently amended in 1999.[6] OAPI was established to promote i) economic and social development needs; ii) harmonisation of laws affecting inventiveness; and, iii) cooperation among the member states. The 16 OAPI member states are predominantly

[5] <http://www.lawyersforafrica.com/oapi.htm> (Cited: 01 September 2010).
[6] WIPO, Administration and Teaching of Intellectual Property. <http://www.wipo.int/about-ip/en/iprm/pdf/ch6.pdf.> (Cited: 01 September 2010).

French-speaking countries. The Bangui Agreement covers patents, utility models, trademarks, industrial designs, trade names, geographical indications, copyright, unfair competition, integrated circuit layouts and plant variety rights. [7]

OAPI is responsible for implementing and applying common administrative procedures, contributing towards the promotion of literary and artistic expression and intellectual property rights, encouraging the creation of copyright bodies in member states and centralising and coordinating information of all kinds relating to the protection of Patents, Trademarks, Literary and Artistic Property.

OAPI operates under a common system of protection of intellectual property which is characterised by uniform legislation applicable in each member state and by centralising administrative procedures at the Organisation based in Cameroon. The Bangui Agreement enables the users to have their rights protected in all member states through a single deposit, which is considered as a national deposit for each member state.

The Bangui Agreement specifically states that schemes, rules or methods for doing business; methods for the treatment of the human or animal body by surgery or therapy, including diagnostic methods; and, computer programs may not be patented. That said, the Agreement caters for the protection of Copyright works. To this end, the Agreement defines "works" to include computer programs. According to definitions in the Agreement, "computer program" means a set of instructions expressed in words, codes, schemes or any other form capable, once incorporated in a machine-readable medium, to carry out or obtain a task or particular result by a computer or by an electronic process capable of processing information. The above definition suggests that components of ART-A technology that relate to diagnostic methods and computer programmes can not be patented in OAPI member states.

## 3. OAPI and ARIPO: Overlap and Common Challenges

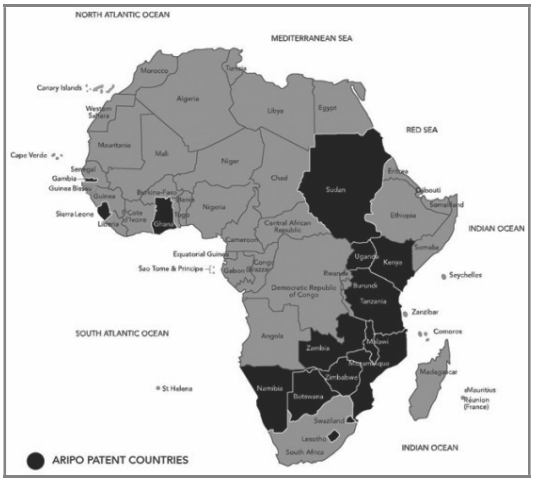
The economic conditions, state of technological development and level of utilisation of the IP protection systems are similar across both OAPI and ARIPO member countries. It is therefore not surprising that both organisations have common challenges and purposes, complementarity being based on similar economic conditions that prevail in both regions. ARIPO and OAPI are both regional systems that work reasonably effectively and operate under conditions whereby member countries still have limited capability in policing and enforcing IP rights. Linked to this is the fact that member countries still have limited IP infrastructures, limited resources to undertake all the objectives and programmes; limited knowledge and information relating to IP among citizens of the member countries; and, limited capacity particularly in the national offices to undertake and adopt policies developed in the region. All ARIPO and OAPI member states are party to the TRIPS Agreement and are members of WTO and therefore are bound by the TRIPs Agreement. As a result, both OAPI and ARIPO allow for the protection of IP rights in multiple jurisdictions in a reasonably clear and efficient manner. It is helpful that WIPO has been supporting African Countries with draft legislations, patent information, awareness drives, etc. While there is interest in WIPO's Development Agenda; [8]there continues to be widespread perceptions that IP is too cumbersome and is therefore for the rich,

[7]< http://www.wipo.int/ip-development/en/> (Cited: 01 September 2010).

[8] Samuel Wangwe et al. Country Case Study for Study 9: Institutional Issues for Developing Countries in IP Policy-Making, Administration and Enforcement. Uganda. Commission on Intellectual Property Rights.

developed countries. Figure 2 provides an illustration of OAPI and ARIPO member states.

In this context it should be noted that the African Union has adopted Africa's Science and Technology Consolidated Plan of Action. The implementation of this Plan of Action includes establishment of the Pan African Intellectual Property Organization (PAIPO). PAIPO is intended to be the EPO equivalent in Africa. However, it is not clear at this stage what will happen to ARIPO and OAPI once PAIPO is created.[9]



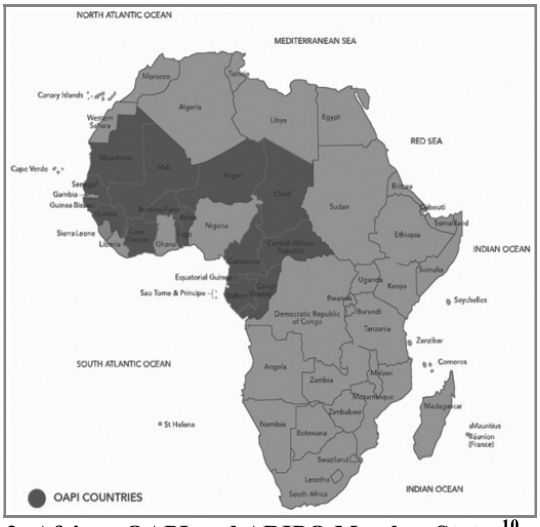




**Figure 2: African OAPI and ARIPO Member States[10]**

[9] Human Resources, Science and Technology, Extraordinary Conference Of The African Ministers of Council on Science and Technology (Amcost), 20 – 24 November 2006, Cairo, Egypt. A Concept Paper: Establishing a Pan-African Intellectual Property Organization, (Paipo).

[10] <http://www.spoor.com/home/index.php?ipkMenuID=&ipkArticleID=115> (Accessed 1 July 2011).

# ANNEX V

# NATIONAL IP INSTRUMENTS:

# UGANDA AND SOUTH -AFRICA

# ANNEX V

# NATIONAL IP INSTRUMENTS: UGANDA AND SOUTH AFRICA

## 1. Uganda

### 1.1. The Policy and Legal Framework for IP in Uganda

The recent history on the development of the national IP legal and institutional framework in Uganda is characterised by a flurry of activities. At independence, Uganda inherited the then existing British IP system, including whole pieces of legislation.[1] This situation continued until the late 1980s to early 1990s when changes began to occur. The period 1990 to-date has been marked by significant changes in the IP legal system, mainly as a consequence of international obligations that were themselves a result of Uganda being signatory to a number of international treaties, conventions and agreements. One such agreement is the World Trade Organisation (WTO) TRIPS Agreement.

In April 1994, Uganda signed the agreement for becoming a member of the WTO and ratified the same in October 1994.[52] By 31st December 1994, the country had fulfilled all the conditions necessary to become a founder member of the WTO.[52] By virtue of being a member of the WTO, the country is bound to fulfil specific obligations that have a bearing on its domestic legislation. Thus the legal regime with regards to commercial laws is affected and, in particular, legislation pertaining to trade-related aspects of intellectual property rights (TRIPS). This means that legislation related to TRIPS will have to be amended and new laws developed to ensure that Uganda's legal regime conforms to international obligations.

The basic objective of the TRIPS agreement is to confer adequate and effective protection to intellectual property rights so that the owner of the rights receives the benefits of creativity and inventiveness. TRIPS covers all seven of the main areas of intellectual property:

- Copyright
- Trademarks
- Geographical indications
- Industrial designs
- Patents
- Layout designs of integrated circuits; and

[1] Ministry of Finance, Planning and Economic Development. The Uganda National Science and Technology Policy, Kampala, 2001.

- Undisclosed information, including trade secrets.

All WTO members are bound by the disciplines of the TRIPS Agreement.

In the year 2000, a task force was put in place to review and up-date the law pertaining to intellectual property rights in Uganda.[53] The task force was set up under the auspices of the Uganda Law Reform Commission (ULRC) and mandated to lead the process of amending and up-dating the law in this regard. The main objectives of the task force are to:

- document and publicise the nature of Uganda's obligations under the TRIPS agreement;
- study existing legislation relating to the TRIPS agreement and establish the need for reform;
- carry out a comparative analysis with foreign jurisdictions in their experience in updating domestic legislation to conform to international obligations under the TRIPS agreement; and
- propose amendments and, where necessary, new legislation to update Uganda's law to conform to her TRIPS obligations.

### 1.2. IP Policy Framework

At the moment there is no specific or concrete national policy on intellectual property rights in Uganda. What could be referred to as the national policy may only be construed from the various pieces of legislation (both substantive and subsidiary legislation) that are currently in the statute books as well as from the various policy statements that can be found in strategic documents of national institutes that touch on the issue. In addition, part of the policy pertaining to IP rights may be, by implication, read in international conventions and treaties to which Uganda is a party , like the TRIPS agreement.

The National Science and Technology Policy[2] provides for the formulation of a policy on intellectual property rights. The specific policy, is yet to be finalised. The various national statutes pertaining to intellectual property rights are discussed in the following section.

**Box ANNEX V-1: *Trips Task Force***

*The TRIPS Task Force mentioned above may be regarded as the main forum through which public policy on IP is currently being developed and formulated in Uganda.* [53] *The main objectives of this task force have been given above and here the focus is on identifying who the key stakeholders are and the nature of the consultation process. The task force, whose activities are being funded by the United States Agency for International Development (USAID), is composed of representatives from the following stakeholders*

- *Uganda Law Reform Commission*
- *Ministry of Justice*
- *Uganda Law Society*
- *The Judiciary (Commercial Court)*
- *Uganda Investment Authority*

[2] Statute No.1 of 1990.

- *Ministry of Tourism, Trade and Industry*
- *Uganda National Council for Science and Technology*

*Representatives from the following organisations / institutions have also been invited to sit on the task force:*

- *Uganda Investment Authority*
- *Uganda Revenue Authority*
- *Private Sector Foundation*
- *Ministry of Finance*
- *Ministry of Foreign Affairs*
- *Ministry of Internal Affairs (the Police)*
- *National NGO Forum*

*It was envisaged that the task force would be fully representative of Ugandan society including civil society and that this would help in the formulation of an IP policy and legal framework that would reflect the expectations of the people. The task force has since been sub-divided into five smaller committees each of which was assigned the responsibility of reaching out to key stakeholders such as:*

- *Publishers, writers and academic writers.*
- *Broadcasters, performers and composers.*
- *Manufacturers, investors, designers and artists.*
- *Herbalists, agricultural researchers and pharmacists.*
- *Administration of justice and law enforcement agencies.*

*Task force members on the various committees are supposed to constantly liaise with these stakeholders and collect their views on the various aspects of IP policy so that they are incorporated into the envisaged policy and legal framework guided by the provisions in the TRIPS agreement.*

### 1.3. Legal Framework

In Uganda there are currently a number of legal provisions pertaining to the administration and enforcement of intellectual property rights. These are contained in the various pieces of legislation that have been enacted since independence in 1962. While a number of these laws have subsequently been amended and/or repealed, others remain intact and outmoded. The following is a sample of the laws pertaining to IP in Uganda today:

***The Uganda National Council for Science and Technology Statute***[54]
This Statute creates the Uganda National Council for Science and Technology (UNCST) which it empowers with the function of protecting intellectual property rights. The Statute also provides for the operation of a National Patent Office by the UNCST.

***The Patents Statute***[3]

The Statute provides for the granting, registration, and protection of patents and for other related matters. It also provides for the registration and protection of IP rights in patents and utility models.

At the moment, proposals are being made to amend or even repeal the Patents Statute to bring it in line with Uganda's international commitments. There is a general view that this Statute should be repealed and replaced with the Industrial Property Bill (2001).[4] This need arises from a multiplicity of developments in IP law on the international scene including a number of treaties and organisations to which Uganda is now a signatory.

***The Copyright Act*** [5]

This law makes provision for copyright of literary, musical and artistic works, cinematograph pictures, gramophone records and broadcasts and related matters.

***The Trade Marks Act*** [6]

This is an Act relating to the registration of Trade Marks. It provides for the appointment of a Registrar of Trademarks (section 3) and the keeping of a register of trademarks (section 4).

***The United Kingdom Designs (Protection) Act*** [7]

The Act provides for the protection in Uganda of designs registered in the United Kingdom.

***The Penal Code Act*** [8]

In as far as IP rights are concerned, the Penal Code defines trademarks and make it an offence for one to infringe on or forge a registered trademark.

***The Trade Secrets Act***

Uganda has a Trade Secrets Protection Act which provides for the protection of undisclosed information in commercial transactions and to provide for other related matters. The Act makes clear the conditions for protection which include information that is not generally known or readily accessible to persons working in the field and information that has commercial value and been subject to reasonable circumstances to keep it confidential.

[3] Statute No. 10 of 1991. See also The Patents Act, Cap 82. Laws of Uganda.

[4] Joan Apecu, Uganda Law Reform Commission, 9 November 2001.

[5] Cap 81, Laws of Uganda.

[6] Cap 83, Laws of Uganda.

[7] Cap 84, Laws of Uganda

[8] Cap 106, Laws of Uganda.

### 1.4. The TRIPS Agreement: Implications for the IP Laws in Uganda

As a result of the activities of the Uganda Law Reform Commission and the TRIPS Task Force, there are a number of Bills and draft Bills in the pipeline targeting provisions relating to IP rights administration and enforcement. These are intended to up-date the Ugandan law to bring it in line with the country's international obligations under the TRIPS agreement. Uganda, along with other Least Developed Countries, are not required to amend their laws to comply with the provisions of the TRIPS Agreement until 2013 and 2016 for pharmaceuticals. The following is a sample of such pieces of legislation that are in the offing:

***The Industrial Property Bill, 2001.***
This Bill provides for the promotion of inventive and innovative activities to facilitate the acquisition of technology through the grant and regulation of patents, utility models, technovations and industrial designs.

The revised Bill was tabled in parliament in 2009 and if enacted into law, would modernise an important part of Uganda's regime of IP law. It covers all industrial property (patents, industrial designs, utility models, and technologies) except trademarks.

***The Patents (Amendment) Bill, 2000.***
The object of this Bill is to amend the Patents Statute (No. 10 of 1991) to give effect in and by Uganda, to the provisions of the Patent Co-operation Treaty signed in Washington in 1970. Uganda is a party to this Treaty. If the changes are effected, they will introduce provisions for processing by the Patents Registry in Uganda of international applications in accordance with an international system under the Treaty whereby a single application made and filed in a country, party to the Treaty, will have effect as an application filed in any other country party to the Treaty. Patent applications are not examined by Uganda's patent office. This function is carried out by ARIPO.

***Uganda Anti Counterfeit Goods Bill 2010***
The Uganda Anti-counterfeit Goods Bill called the East African Counterfeit Bill 2010 (EAC Bill) being is expected to supersede all national legislation pertaining to counterfeit goods. The Bill provides a wide definition of counterfeit goods that includes generic medicines.[9] If the EAC Bill were to be passed into law, it would affect access to life-saving medicines as it indiscriminately treats generic medicines as counterfeit goods as it would prohibit the release of counterfeit goods into the channels of commerce, and make it an offence to trade in counterfeit goods. It would also empower the Commissioner of Customs and the Uganda National Bureau of Standards (UNBS) to seize and detain suspected counterfeit goods. [10]

[9] <http://allafrica.com/stories/201007080864.html> (Cited: 30 November 2010>
[10] H. Wasswa, 'Ugandan patients don't get the AIDS drugs they need', *BMJ*, 2008, Vol. 336, p. 7640.

# 2. South Africa

## 2.1. The Policy and Legal Framework for IP in South Africa

Relative to other developing countries, South Africa has a progressive Intellectual Property policy and legal framework. Legislation pertaining to Intellectual Property cover patents, industrial property, copyright, registered designs, geographical indications and trademarks. Intellectual property falls under four separate headings; patents, trademarks, designs, plant breeders rights and copyrights. In each case the regulations and requirements for the various types of intellectual property are governed by Acts of Parliament. Some of the weaknesses in South Africa's patent system are first, that patent enforcement is inadequate; and second, that it is a non-examining country. The patent application form or documentation is verified but not the substance of the product or process. This means that patents applied for are not investigated for their novelty or inventive merit.

The primary focus of IP policy development in South Africa has been economic development and knowledge dissemination, which is designed to stimulate further innovation.

**Box ANNEX V-2** ***: South African National R&D Strategy of 2002***

*One of the early policies that highlighted the importance of intellectual property in technology and innovation is the South African National R&D Strategy of 2002.* [11] *The National R&D Strategy set out to develop competencies in intellectual property rights that would address the shortcomings in the IP system. One of the strategic initiatives that the Strategy set out to accomplish is to develop an IPR policy framework for IP generated by publicly funded R&D. Policy issues that were considered at the time included:*

- *Securing intellectual property on the outputs of publicly financed research*
- *Giving preference to non-exclusive licensing*
- *Giving preference to local licensing*
- *Giving preference to Small Medium Enterprises (SME) and Black Economic Empowered individuals as licensors*
- *Defining benefit sharing with inventors.*

Intellectual Property features in a number of other areas of South African policy. This includes:

[11] The Department of Science and Technology. The South African National R&D Strategy of 2002. 2002.

- **Tax law.** – The laws allow for entities and individuals to derive income from patents and similar property, over a period, by deducting from taxable income, expenditure on: [12]
  −devising and developing an invention;
  −generating or making a design, trademark, copyright or similar asset;
  −registering or obtaining a patent, design registration or trademark; and
  −acquiring from someone a copyright, design, patent, trademark or similar property.

- **Competition law** – The purpose of South Africa's Competition Act is to "promote and maintain competition." [13] The Act is supplemented by six particular sets of goals. The first of these is the efficiency, adaptability, and development of the economy. The second goal, competitive prices and choices for consumers, recognises the foundation of an economics-based policy in concerns of consumer welfare. The other 4 sets of policy goals represent other public interest issues that have been important to stakeholders in the debate namely, employment and social and economic welfare, opportunities to participate in world markets (and to recognise foreign competition in South Africa), equitable opportunities for SMEs to participate in the economy, and increasing the ownership stakes of historically disadvantaged persons.

  In the 2003 lawsuit case initiated by about 40 pharmaceutical companies objecting to changes proposed in South Africa's Medicines and Substance Control Act, the South African Competition Commission found two of the pharmaceutical companies at fault for abusing their dominance in the AIDS medicines market by denying competitors access to essential facilities, charging excessive prices and engaging in exclusionary acts. The companies concerned were believed to be using their exclusive rights in the patents they owned to deny appropriate licences to other manufacturers. At the end, the case was settled without resolving the complex legal issues. However, the outcome after the settlement was a significant decrease in HIV drug prices, the issuance of new voluntary licenses and a decrease in rights to royalty payments. In this instance, the anticompetitive behaviour by big pharma was used as a vehicle to improve access to essential medicines.[14] Whilst this is an alternative approach to the compulsory licensing route, it is not a simple one as it entails highly technical and complex negotiating.

### 2.2. IP Policy Framework

IPRs are very much a part of government policies aimed at promoting creativity and the dissemination of technological innovation as a result of social and economic development.

[12] The Government of South Africa. [Online] <http://www.info.gov.za/view/DownloadFileAction?id=71070> (Cited: 03 September 2010).
[13] OECD. <http://www.oecd.org/dataoecd/52/13/2958714.pdf.> Organisation for Economic Co-operation and Development, 2003.
[14] Jerome Reichman. *Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options.* 2009. 37 J.L. Med. & Ethics 247

In 2008, the Intellectual Property Rights from Publicly Financed Bill[15] was promulgated into law. The IPR Act is a significant milestone in South Africa's history of intellectual property rights protection. The purpose of the IPR Act is to make provision that intellectual property emanating from publicly financed research and development is identified, protected, utilised and commercialised for the benefit of the people of the South Africa, whether it be for a social, economic, military or any other benefit. The Act seeks to:

- provide for more effective utilisation of intellectual property emanating from publicly financed research and development;
- establish the National Intellectual Property Management Office and the Intellectual Property Fund, and;
- provide for the establishment of offices of technology transfer at institutions; and to provide for related matters.

The objectives of the above Act are ambitious and aim to address many of the challenges relating to the protection and management of national IP, that exist in the country and its National System of Innovation in respect of exploiting IP derived from publicly funded research.

An important passage, especially for the ART-A research project, of the IPR Act is Clause 15 which deals with determinations on Intellectual Property Rights ownership with respect to co-financing of research and long term research partnerships. The IPR Act states that private entities may only own intellectual property rights if the research and development concerned has been funded on a full cost basis by the private entity. According to the Act, Full Cost means the 'full cost' of undertaking the research and development which includes both direct and indirect costs. Furthermore, the Act defines a private entity to include a private sector company, a public entity, an international research organisation, an educational institution or an international funding or donor organisation. The ART-A research project is subject to the conditions of the Act, since consortium research is being conducted in South African institutions. In terms of this act, a South African institution involved in ART-A research would automatically have co-ownership of any IP developed unless ART-A is paying that institution full costs for its role in the research and development. This is irrespective of any separate IP arrangements existing between the South African institution and other ART-A consortium members. The conditions of the Act apply to IP developed prior to proclamation of August 2, 2010 but being transacted post the August date.

### 2.3. IP Legislation in South Africa

As discussed earlier, South Africa has a well established and mature intellectual property system. The various Acts that cover industrial designs, copyright, patents and trademarks are summarised next.

***The Designs Act 195 of 1993***[71] The Designs Act caters for the registration of both aesthetic and functional designs. In the case of aesthetic designs, the design needs to be

[15] South African Goernment. Intellectual Property Rights from Publicly Financed Act. [Online] 2008. <http://www.info.gov.za/view/DownloadFileAction?id=86995> (Cited: 03 September 2010).

new and original, whereas functional designs must be new and non-commonplace. Designs are formally registered and the Act provides for the requirements for registration.

***The Copyright Act 98 of 1978 as amended***[16]

South Africa is party to the Berne Copyright Convention which lays down basic principles of copyright law that all member countries have to comply with. The Copyright and related rights Act makes provision for the protection of literary, music, artistic works and cinematograph films, sound recordings, broadcasts, programme-carrying signals, published editions and computer programmes. The Act also deals with moral rights in copyright material, ownership of copyright, infringements of copyright and remedies that an owner of copyright can seek in the case of infringement.

***The Patent Act 57 of 1978 as amended***[17]

The Patent Act applies to the protection of any new invention which involves an inventive step and which is capable of being used or applied in trade, industry or agriculture. Therefore, under the Patent Act, inventions must comply with the international requirements for patentability which are novelty, an inventive step and a use or application. An invention can be a new product, process, device or the like, or an improvement on an existing product, process, device or the like. The Act specifically excludes a discovery, scientific theory, methods of medical treatment, mathematical method, an aesthetic creation, a scheme, rule of method for performing a mental act or doing business, a programme for a computer or the presentation of information as inventions. South Africa registers patents but does not examine patent applications.

***The Trademarks Act 194 of 1993 as amended***[18]

Trademark protection relates to the protection of goods and services, to distinguish them from others. Trademarks are intended to serve as an indication of consistent quality of a product or service. In South Africa, Trademark laws include collective marks and certification marks. Collective marks are defined as signs which distinguish the geographical origin, material, mode of manufacture or other common characteristics of goods or services of different enterprises that use the collective mark. Certification marks relate to a compliance with certain standards. They may be used by anyone who can certify that the products involved meet certain established standards. In many countries, the main difference between collective marks and certification marks is that the former may only be used by a specific group of enterprises, e.g., members of an association, while certification marks may be used by anybody who complies with the standards defined by the owner of the certification mark. An important requirement for certification marks is that the entity which applies for registration is considered "competent to certify" the products concerned.

[16] <http://www.publishsa.co.za/downloads/copyright_act.pdf> ( Cited: 03 September 2010).
[17] <http://www.cipro.co.za/legislation%20forms/patents/patent%20act.pdf> (Cited: 03 September 2010).
[18] The South African Government.
<http://www.cipro.co.za/legislation%20forms/trade%20marks/Trademark%20Act.pdf> (Cited: 03 September 2010).

## 2.4. Copyright Protection and Software

As mentioned above, the South African Copyright Act 98 of 1978 lists computer programmes as works eligible for copyright protection. For works to be eligible for protection they must be written down, recorded, represented in digital data or signals or otherwise reduced to material form. A computer programme is defined as:
*"A set of instructions fixed or stored in any manner and which, when used directly or indirectly in a computer, directs its operation to bring about a result"*

What this means is that any code which can be used to operate a computer qualifies as a computer programme and would be protected by the law of copyright.

Further criteria that must be met before copyright will subsist in a work are that it must be original, exist in a material form and have been created by a qualified person. [19]

Examples of subject matter than can be protected under copyright protection of computer programmes include copyright residing in the source code of a computer programme. With ever increasing changes in software to meet higher customer expectations and the resulting use of complex software design and capability to create software code, means that protection offered by the South African Copyright Act is very limited. Therefore a need has arisen to protect software related inventions through other legal instruments such as the Patent Act. At present, the South African Patents Act excludes a programme for a computer, as such, from the definition of an invention. As with all other inventions, computer programmes must be new, inventive and have a use or application in trade, industry or agriculture. To overcome objections as to whether the programme or apparatus involves an inventive step, it may be helpful to determine the technical problem that is being solved through use of the programme. The presence of such a technical contribution is usually sufficient to establish that the claimed subject-matter has a technical character and therefore is indeed a patentable invention. If no such objective technical problem is found, the claimed subject-matter does not satisfy the general requirements for patentability and may be patented.[20] There has been no litigation in South Africa on the specific section in the South African Patents Act dealing with the exclusion of software from patentability.[21] Therefore, there is no clear indication of the interpretation that the courts would adopt to this section of the Patents Act. Apart from the traditional protection provided by the South African Copyright Act and the protection provided by the South African Patents Act, other forms of protection for computer related inventions should be considered such as contractual agreements. [79]

According to the Copyright Act and with reference to computer programmes, the owner of the copyright programme is not infringed when a person who is in lawful possession of the computer programme makes copies of the computer programme for back-up purposes and when such a copy is intended for personal and private purposes.

[19] Spoor and Fischer. [Online] < http://www.spoor.com/home/index.php?ipkMenuID=&ipkArticleID=272 > (Cited: 01 September 2010).
[20] Smit and Van Wyk. [Online] < http://www.svw.co.za/software.html> (Cited: 01 September 2010).
[21] Ethel Teljeur, 'Intellectual Property Rights in South Africa: An Economic Review of Policy and Impact', The Edge Institute, South Africa, 2003.

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